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The value of the Hospital Episode Statistics to study practice and outcome of urological surgery

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**Thesis for the degree of Doctor of Medicine (MD)
University of London**

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IN

ORIGINAL

Statement of originality and involvement

This work has not previously been accepted in any substance for any degree and is not currently submitted in candidature for any degree.

This thesis is the result of my own investigations, except where otherwise stated.
Other sources are acknowledged by explicit references. A bibliography is appended.

I hereby give consent for my thesis, if accepted, to be made available for photocopying and inter-library loan, and for the title and abstract to be made available to outside organisations.

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Date

Journal Publications arising from this research

Trends in paediatric circumcision and its complications between 1997 and 2003 in England.

Cathcart PJ, Nuttall M, van der Meulen J, Emberton M. Kenny S.

Br J Surg. 2006 93(7): 885-90

The Incidence of primary and recurrent Acute Urinary Retention between 1997 and 2003 in England.

Cathcart PJ, Armitage J, van der Meulen J, Emberton M

Journal of Urology J Urol. 2006 176(1): 200-4

Presentations to learned societies arising from this research

Time to cystectomy – its influence on overall survival.

American Urological Association Annual meeting, Atlanta, Georgia, USA, 2006

European Association of Urology, Paris, France, 2006

The impact of hospital provider volume on the outcome of radical cystectomy in the UK.

American Urological Association Annual meeting, Atlanta, Georgia, USA 2006

European Association of Urology, Paris, France, 2006

The impact of age and co-morbid disease on the outcome of radical cystectomy.

European Association of Urology, Paris, France, 2006

The impact of hospital provider volume on the outcome of radical nephrectomy in the UK.

European Association of Urology, Paris, France, 2006

Has the decline in surgical treatment for BPH resulted in an increase in the incidence of AUR?

European Association of Urology, Paris, France, 2006

British Association of Urological Surgeons Annual Conference, Manchester, UK, 2006

Relapse in acute urinary retention following its first occurrence.

European Association of Urology, Paris, France, 2006

Trends in Surgical Repair of Hypospadias in England between 1997 and 2004. British Association of Urological Surgeons Annual Conference, Manchester, UK, 2006

The declining frequency of circumcision in England.
European Association of Urology, Istanbul, Turkey, 2005

Complications of circumcision in England. British Association of Paediatric Surgeons, London, UK 2005

The frequency of hospital admission for AUR in England.
British Prostate Group bi-annual meeting, York, UK 2005

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Abstract

Introduction

Despite the growing emphasis on the collection, monitoring and reporting of outcomes of surgical care within the UK, few data exist for such purposes. Equally, few data are available on disease occurrence and surgical practice in England. In this thesis, the hypothesis that Hospital Episode Statistics (HES) data can be used for such purposes is tested.

Methods

The objectives of this thesis were twofold. Firstly, to review the literature to establish to what extent HES data has been used to study incidence, surgical treatments and their outcomes. Secondly, to evaluate - using a number of individual HES-derived case studies, to what extent the HES database can be utilised to answer clinical questions concerning incidence, practice and outcome of urological surgery.

Strengths and weaknesses of the HES database were subsequently sought on which to generate recommendations concerning the future clinical use of the database.

Results

The review highlighted the completeness of the database identifying very low under-ascertainment when compared to local audit data although did identify that use of Finished Consultant Episodes (FCE'S) resulted in over-estimation of disease incidence.

HES-derived case studies suggested, first, the incidence of hypospadias was considerably higher than previously reported and furthermore, did appear to be on the increase. Second, boys continue to undergo clinically inappropriate foreskin surgery. Third, the shift away from surgery for men with symptomatic BPH has not resulted in more men experiencing an episode of acute urinary retention. Fourth, high-volume cancer centres appear to achieve improved outcomes following cystectomy by reducing the risk of "failure-to-rescue" following an adverse event.

Recommendations on the future clinical use of HES data drawn from the HES-derived case studies were first, if incidence is to be calculated using HES data, there must be no or minimal ambiguity regarding diagnostic or procedural coding. Second, a number of diagnostic and procedural codes can be “operationalised” to define an event provided coding practice is not identified in advance. Third, the incidence of a condition can be identified using HES data provided all patients or at least the majority of patients undergo hospital treatment for that condition. Fourth, for HES data to comment on clinical appropriateness of treatment, the prevalence of the condition requiring treatment must be known. Fifth, if HES data is to be used to analyse trends in disease incidence over time, there must be no changes in coding practice over the study period. Sixth, HES data should not be used in isolation to report long-term oncological outcomes. Seventh, HES data is suitable to investigate the determinants of short-term surgical outcome such as mortality.

Conclusion

Evaluation of the use of HES data to answer specific questions concerning the incidence, practice and outcome of urological surgery suggests HES is a useful source of data provided caveats concerning the strengths and weaknesses of the database are considered at the time of data analysis.

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Section 1

Introduction and General Overview

Chapter 1

Introduction

1.1 Introduction and Objectives of thesis

This thesis describes work I undertook during a 24-month period as a research fellow attached to the clinical effectiveness unit at the Royal College of Surgeons of England. The thesis is divided into four sections, each sub-divided into chapters describing different aspects of this work.

The objectives of this thesis were twofold. Firstly, to review the literature to establish to what extent Hospital Episode Statistics (HES) data has been used to study incidence, surgical treatments and their outcomes. Secondly, to evaluate to what extent the HES database can be utilised to answer clinical questions concerning incidence of urological disease as well as practice and outcome of urological surgery.

Section one consists of two chapters. The first chapter is a general introduction to the thesis while the second chapter contains a summary, for non-urological readers, of Hypospadias, Phimosis, BPH and Bladder Cancer as well as the surgical procedures employed to treat such conditions.

Section two consists of two chapters. The first chapter presents a general overview of the HES database while the second chapter presents a review of the published literature to establish, first, to what extent the HES database of the Department of Health in England has been used to report on the incidence of surgical disease and second, to what extent the HES database has been utilised to report on the determinants of outcome following surgical activity.

Section three of this thesis included five case studies specifically chosen to evaluate the use of the HES database as a source of data for the urologist to answer clinically relevant and important questions concerning incidence of urological disease, surgical treatments and their outcomes.

The first two case studies within this section considered two paediatric urological procedures, namely Hypospadias repair and circumcision. The first case study used HES data concerning surgical treatment of hypospadias, to report trends in the

incidence of the congenital anomaly and subsequently compared incidence based on treatment to that reported by the national congenital anomaly register.

The second case study used HES data to identify the incidence of circumcision in England. Given that the prevalence of phimosis – almost the only true medical indication for medical circumcision in the paediatric population, is so well documented, HES data was used in this case study to evaluate the clinical appropriateness of surgical treatment for the condition.

The third case study utilised HES data to comment on trends in the incidence of acute urinary retention – a known complication of Benign Prostatic Hyperplasia (BPH), to investigate the impact of change in the management of BPH.

The fourth case study used HES data to investigate whether delay in radical urological cancer surgery resulted in poorer long-term oncological outcomes in patients with invasive bladder cancer.

The final case study used HES data to investigate how higher volume cancer hospitals achieve improved short-term peri-operative outcomes, again following radical urological cancer surgery.

Section four of this thesis comprises a general discussion in which the use of the HES database to answer clinical questions concerning the incidence of urological disease and the determinants of outcome following urological surgery are evaluated. In this last section, the strengths and weaknesses of the HES database are discussed in the context of the review and the individual case studies. These findings are subsequently compared with those gained from studies that have investigated the use of databases other than HES for similar purposes.

Drawing on the findings of this thesis, specific conditions are identified that need to be met before the HES database may be used as a source of information for the urologist. These conditions are subsequently summarised in a number of recommendations. The types of clinical questions that the HES database may be most suited to answer are then discussed.

Finally, the aim of this thesis was to evaluate to what extent the HES database can be utilised to answer clinical questions concerning the incidence of urological disease as well as practice and outcome of urological surgery

1.2 Background

Quality within the context of healthcare provision has recently been defined in the Lord Darzi review - High Quality Care for All: NHS Next Stage Review Final Report [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085825]. This review, commissioned by the Department of Health in England, stated that quality should be defined and so evaluated according to three aspects of care, namely, patient safety, patient experience and finally, effectiveness of care.

Defining what quality is, represents the first key step in improving healthcare provision as once quality can be defined, data on can be collected, systematically measured and subsequently published [Lakhani et al, 2005].

The framework or system through which organisations such as the National Health Service (NHS) achieve and continuously improve the quality of their care is collectively referred to as clinical governance [www.dh.gov.uk]. Clinical governance activities have always been an important aspect of clinical medicine, however, increasing emphasis has been placed on such activities in the United Kingdom following recommendations drawn from the Bristol inquiry – an independent public inquiry into paediatric cardiac mortality rates at the Bristol Royal Infirmary [www.Bristol-inquiry.org.uk]. Currently, all doctors working with the NHS are contractually obliged to participate in clinical governance activity while the General Medical Council (GMC) lists such activity as an essential aspect of “Good Medical Practice”, a code of conduct published by the organisation.

It is well recognised that data concerning all three aspects of quality of healthcare provision are lacking in the UK, despite quality improvement being the key tenet of clinical governance [Aylin et al, 2001] and the widely held belief that it is only through the process of data collection and data reporting that the quality of care within the NHS is likely to improve [Lakhani et al, 2005].

It is to be expected that few data are available concerning patient experience as this aspect of quality has been neglected in the past, only being highlighted in the recent

Darzi report. However, it is disappointing that there remains a lack of data concerning the two other aspects of healthcare quality, namely clinical effectiveness and patient safety in the UK.

At the same time, patients and government alike have been increasingly demanding transparency with regard to quality of care. A recent NHS chief executives report commented on the “constraints of current measures of quality and productivity and on the need for better measures of output and outcome” [DOH, 2004]. This view was reinforced by a recent review of government outcome and productivity which acknowledged a “lack of measures of output and outcome within the NHS” [Atkinson et al, 2004]. Such reviews are important, as government is keen not only to ensure improving standards within the NHS, but also to identify the gains achieved by increasing public spending within the service. Patients on the other hand are increasingly demanding data concerning quality of care so as to enable informed decision making when deciding on their own medical treatment.

The monitoring of surgical outcomes in an attempt to report effectiveness of care and patient safety, requires complete, timely and accurate data that will in turn help identify factors that contribute to variations in quality [Nuttall et al, 2007]. As mentioned earlier however, this data is lacking on a large scale in the UK [www.ncl.ac.uk/qip, Gill et al, 2003]. For this reason, information on the quality of surgical care is predominantly generated by relatively small ad hoc studies. Such studies, traditionally carried out by the individual surgical specialty associations, have often suffered from limited funding, lack of essential resource and support [Fine et al, 2003]. Recently, a small number of large-scale national audits were initiated and sponsored by the Healthcare Commission to address mainly NHS priorities [Healthcare commission, 2004]. However, these audits are expensive and labour-intensive projects and therefore understandably, only a limited number of surgical problems and interventions can ever be investigated in this way [Measuring and Using outcomes of Surgery: www.rcseng.ac.uk].

The Bristol Royal Infirmary inquiry [www.Bristol-inquiry.org.uk] report made 198 recommendations that concerned many aspects of clinical care applicable to all clinician's not only cardio-thoracic surgeons. Key recommendations from the inquiry

included the need for periodic revalidation, the need for the development of national standards of care, the increased transparency of sentinel event reporting as well as the creation of regulatory bodies to regulate healthcare standards and institutions. The report also stated that patients and the public alike should be able to obtain information as to the relative performance of trusts and the services and consultant units within such trusts. This last issue essentially called for increasing transparency concerning the collection and reporting of surgical outcomes.

While the Bristol inquiry was ongoing, cardiac surgeons in the UK had foreseen the increasing requirement for the collection and reporting of national audit data [Keogh et al, 2004]. As a direct result of this insight, the Society for Cardiothoracic Surgery in Great Britain (SCTS) developed a highly detailed national database – the Central Cardiac Audit Database (CCAD) for the collection of national surgical outcomes [Fine et al, 2003]. The Society made it compulsory that all surgeons performing cardiothoracic surgery in the UK provide their own detailed audit data to the CCAD. Collection of such data has allowed the SCTS to monitor quality of surgical care within the UK using risk adjusted models that in turn have been published to inform the government and patients alike [Bridgewater et al, 2005]. Furthermore, Bridgewater and colleagues [2007] have demonstrated that data collection and subsequent publication of cardiac surgery mortality data in the UK has itself resulted in a decreased mortality following such surgery, a trend not associated with fewer high risk patients being operated upon.

While such a policy on data collection is highly admirable and highly desirable, it is not practical or cost-effective to collect such detailed audit data on all surgical procedures completed within the NHS. It is therefore important to consider alternative approaches to provide data of adequate quality at relatively low cost across the breadth of surgery.

In the US, a growing number of studies on the quality of surgical care are published based on administrative data [Romano et al, 2002]. Most studies use such administrative data to report effectiveness of surgical care. An administrative database

that is often used in the US is the Medicare database. This database encompasses the Medicare claims of 97% of individuals aged 65 or older. The HES database, containing information about all admissions in NHS Trusts, is an English equivalent of the US Medicare database.

In contrast to its American counterpart, the HES database has historically been used relatively infrequently to report on effectiveness of care in the UK - although of late this trend is increasingly being reversed. There are several reasons why the HES database has not tended to be used to report on this aspect of quality of care. First, there are concerns about the accuracy of the HES data, although there is limited evidence to underpin this. For example, a recent systematic review including studies comparing HES records with case notes in the UK only retrieved studies that examined the period before the introduction of the ICD-10 in 1995 [Campbell et al, 2001]. Most of these studies used methods of variable quality, were performed in a limited number of centres, and included a small number of patients.

Second, the HES database is less detailed than the databases used in the US, because the latter are generated as a component of a prospective payment system. Despite this, there is clear evidence that coding of additional or secondary procedures, as well as coding of pre-existing comorbid disease within the HES database is increasing. In 1993, although it was possible for an additional six secondary diagnoses, other than the primary diagnosis to be recorded within the database, as a result of a policy of only documenting a secondary diagnosis in '*special circumstances*', only a small number of HES records actually had a documented secondary diagnosis pertaining to a complication occurring during admission or comorbid pathology (2 million) [www.hesonline.nhs.uk]. However, having changed coding policy to document and code for all additional diagnoses, as well as increasing the number of secondary diagnoses capable of being recorded within the database – 14 diagnosis fields were introduced in 2002, by 2004, more than 20 million secondary diagnosis codes were listed within the 13 million patient records included in the database that year.

Third, comparisons (among providers or between different types of treatment) based on HES data may be misleading as the HES database contains only limited information on disease severity and comorbidity.

Despite the above concerns, the HES database would appear to have considerable potential for the investigation of surgical outcomes and quality of surgical care with specific regard to patient safety and effectiveness of care, in the UK. It is population-based, highly representative of its population, and given that it routinely collected by the UK government and has been since 1989, it represents a cheap source of data spanning more than 15 years. Furthermore, it is readily available and relatively low cost. As such, the HES database would appear to represent a much under-utilised epidemiological resource.

The advantages of HES database listed above, also make the database potentially useful, not only for investigating quality of surgical care, but also for the evaluation of disease occurrence within the UK. Again the US counterpart to the HES database – Medicare, has been utilised extensively for this purpose [Baron et al, 2000].

Identification of disease occurrence may be of great importance for ‘healthcare needs assessment’, evaluation of public policy, detection of change in health practices and the effects of these changes, as well as the evaluation of the natural history of disease. [Farmer et al, 1998, Teutsch et al, 1994].

However, alike surgical outcome reporting, few data exist on disease occurrence within the UK while those studies and systems designed to do so are again highly labour-intensive and therefore expensive [Dolk et al, 2004].

1.2.1 Origin of this Thesis

The Clinical Effectiveness Unit (CEU) of the London School of Hygiene and Tropical Medicine and The Royal College of Surgeons of England has been developing a programme of work to study the “epidemiology of the quality of surgical care”. Its aim is to provide quantitative information on processes and outcomes of surgical care as well as their determinants.

Part of this ongoing research programme is the evaluation of alternative data sources to answer specific clinical questions. While the randomised controlled trial (RCT) is generally regarded as the gold standard research methodology for answering clinically significant research questions, there are many situations where the RCT is not feasible or ethical to conduct [Joffe et al, 1994, Leyland et al, 1991]. Data from RCT's are often limited to the specific question being asked while the strict criteria for RCT entry often raises concerns regarding the applicability of RCT results to everyday practice. It is in this context that alternative data sources such the HES database may have great potential.

With these issues in mind, the purpose of this thesis was to evaluate to what extent the HES database may be used to answer specific pre-determined clinical questions. These questions were broadly divided into those that evaluate the use of the HES database as a source of data to report on the incidence of urological disease, and those that evaluate the use of the HES database as a source of data to report on patient safety and effectiveness of surgical care – two of the three tenets of quality.

Within this thesis, these clinically important, pre-determined questions take the form of case studies. It must be stressed that at the heart of our methodology lies the fact that all questions be pre-determined prior to data review. It is through these case studies that the HES database is evaluated as a source of data for clinical use.

The focus of this thesis concerns urological disease and urological surgery, however, conclusions generated within this thesis concerning the clinical use of HES data to answer clinically important research questions are likely to be relevant for all surgical care.

1.2.2 Case Studies

Section three of this thesis included five case studies specifically chosen to enable the evaluation of the HES database as a source data to ask clinically important questions. Such evaluation is the subject of section four of this thesis.

The first of these case studies addresses the clinical question - is the incidence of hypospadias, a congenital anomaly affecting the male urethra, on the increase?

This is a clinically important question as there is evidence to suggest the incidence of hypospadias may be rising as a result of increasing environmental exposure to environmental pollutants [Paulozzi et al, 1997]. However, in England, due to concerns regarding the accuracy and validity of pre-existing congenital anomaly systems, as highlighted in a recent validity study [www.eurocat.ulster.ac.uk], it is not possible to verify if such a trend is occurring. This case study therefore attempts to compare incidence based on treatment, captured in HES with that reported in the congenital anomalies register.

The second case study included within this thesis addresses the clinical question – are too many boys undergoing paediatric circumcision for phimosis of the foreskin in England?

A number of well-conducted studies have reported on the incidence of pathological phimosis in England [Rickwood et al 1989, Dewan et al, 1996]. In this case study, the use of HES data to complement pre-existing data on disease incidence was evaluated to identify if boys continue to undergo clinically unnecessary surgery. In such a way, HES was used to evaluate the clinical appropriateness of treatment.

The third case study included within this thesis concerns the incidence of acute urinary retention – a known complication of Benign Prostatic Hyperplasia (BPH) progression. Clinical management of BPH has changed significantly over the last decade due to advances in pharmaceuticals [Kirby et al, 2000]. This in turn has resulted in far fewer men undergoing surgery for the disease. However, little is known about the impact of such a change on disease progression. Acute urinary retention is one consequence of BPH disease progression [Barry et al, 2001]. The third case study within this thesis asks the question - what is the impact of a shift away from surgery towards medical therapies for the treatment of men Benign Prostatic Hyperplasia on the incidence of acute primary urinary retention?

The fourth case study asks the question – does delay in the time from diagnosis of advanced bladder cancer to the time of definitive cancer treatment impact on the long-term oncological outcome of such cancer treatment?

A number of clinical studies have reported that delays of more than 3 months between diagnosis and definitive treatment can infer a worse outcome following subsequent radical surgery for bladder cancer patients [Chang et al, 2003, Mahmud et al, 2006]. This study evaluates if the HES database, with its inherent lack of data concerning oncological variables, can be used to demonstrate similar findings. If HES data were unable to establish a trend of worse outcome in relation to preoperative delay,, it would subsequently cast doubt on the use of HES data to report on long-term outcomes cancer treatment without the need for linkage with other data sources such as pathological databases.

Evaluating the use of the HES database to answer questions concerning the impact of administrative variables such as operative delay is of increasing importance. Government is generating an increasing number of targets concerning cancer treatment, the impact of which we are currently unable to evaluate through local audit. Furthermore, with the increasing centralisation of cancer services within the UK, as advocated by government for radical pelvic cancer surgery for example, the impact of administrative variables such as pre-operative delay will be increasing importance as patients will have to travel longer distances to receive treatment.

The fifth and final case study reported on within this thesis asks the question - how do higher volume hospitals achieve improved outcomes following radical cystectomy for bladder cancer?

Considerable data are available reporting the association between volume and outcome, not only for urological surgery but also for a number of other non-urological surgeries [Birkmeyer et al, 2002, Goodnet et al, 2003]. However, as yet, there are few data investigating how such a correlation is achieved. In this fifth and final case study included within the thesis, the HES database is evaluated for its ability to uncover the cause and effect of such a volume and outcome relation.

In summary, with the growing emphasis on clinical governance throughout the medical profession, there is an increasing demand for the monitoring of clinical outcomes so as to maintain and improve the quality of care within the UK. Despite this, there is a lack of data available on patient outcomes within the UK. At the same time, there is also a lack of data concerning the volume of disease within the UK that needs clinical care. This thesis explores the use of the HES database, an example of a routinely collected data source, collected for the purpose of administration, to answer specifically designed clinical questions concerning the incidence of disease within the UK as well as provide quantitative information on the processes and outcomes of surgical care.

1.4 Practical Considerations

For the purpose of this project, the Clinical Effectiveness Unit (CEU) established a collaboration with the HES Section of the Department of Health. The Director (Professor Jan HP van der Meulen) and the Clinical Director (Mr Mark Emberton) of the CEU appointed a research fellow (Mr Paul Cathcart), who had completed basic surgical training, who would be responsible for the day-to-day management and coordination of the project for two years. The entire study was funded by the Research Fellowship Scheme of The Royal College of Surgeons of England.

The Clinical Effectiveness Unit at The Royal College of Surgeons of England is an academic collaboration between the Health Services Research Unit of the London School of Hygiene and Tropical Medicine of the University of London and The Royal College of Surgeons of England. It is the remit of the CEU to study “the epidemiology of the quality of surgical care”. The CEU was established in 1996, replacing the Surgical Audit and Epidemiology Unit.

The vast majority of work within this thesis has been undertaken by me. However, in the course of conducting this work, I have worked within a team consisting on my supervisors, Mr Mark Emberton and Professor Jan van der Meulen, in which all three of us contributed ideas to this work. I performed all analyses presented in this work, although statistical and methodological guidance was provided by Professor Jan van der Meulen. All literature searches and background research was conducted by me,

and the entire text has been written by me under the guidance of my supervisors. This thesis represents original work, although some aspects of this work have been based on methods used by other workers and where this is the case, appropriate references have been made.

Chapter 2

Summary of the urological diseases and urological surgeries on which the case studies included within this thesis are based

2.1 Objectives

The objectives of this chapter were to describe in brief the urological diseases and urological surgeries on which the case studies included within this thesis are based.

2.2 Description of the Diagnosis and Treatments for Hypospadias

2.2.1 Diagnosis of Hypospadias

The first case study within this thesis concerns hypospadias. This is the medical term applied to a congenital penile anomaly in which an abnormal ventral opening of the urethral meatus is identified. This defect is often associated with two further findings, namely, a ventral curvature of the penis known as chordee and a hooded foreskin that is in turn deficient on the ventral aspect of the penis [Thomas et al, 2002, Gallentine et al, 2001].

Many theories have been suggested in an attempt to explain the aetiology of hypospadias. These include deficiencies in hormonal stimulation of the penis, genetic disorders and vascular anomalies. A genetic link has been suggested by the finding that the condition appears more common in monozygotic twins as well as the offspring of fathers who have hypospadias themselves [Thomas et al, 2002, Vrijheid et al, 2003, Gatti et al, 2001].

Hypospadias is associated with another congenital anomaly, namely undescended testes in which the testicle fails to descent from the posterior abdominal wall into the scrotum during later stages of pregnancy. Furthermore, this association appears to be more apparent in those with severe or more proximal hypospadias.

Hypospadias has been traditionally described according to the site of the abnormal meatus. As such, hypospadias is described as distal - where the meatus lies either on the glans or the coronal sulcus, mid-shaft or peno-scrotal – where the meatus opens

onto the proximal penis or the perineum. Distal forms are by far the commonest [Thomas et al, 2002, Vrijheid et al, 2003].

2.2.2 Treatment for Hypospadias

Surgery is indicated in the majority of boys with hypospadias – excluding those with mild glanular hypospadias, as the deformity will often interfere with voiding or subsequent sexual function in latter life. Currently, surgery tends to be performed on boys between 6 and 12 months of age.

There are a number of different hypospadias repairs, the most common of which are the MAGPI and Snodgrass repairs [Manzonni et al, 2004].

Meatal Advancement and GlanuloGlasty or MAGPI is a single stage procedure for milder more distal forms of hypospadias while the Snodgrass procedure, again a single stage procedure, is reserved for more proximal forms.

The results of hypospadias surgery depend on the original defect as well as the type of surgical procedure employed. A number of complications of hypospadias are commonly recognised that include bleeding, infection and subsequent urinary fistula formation. Complications are relatively common (15%) following hypospadias surgery with complication rates being considerably higher when boys undergo surgery for more proximal forms. Complications will often result in the child requiring additional hypospadias procedures.

2.3 Description of circumcision and the diseases treated by the procedure

2.3.1 Circumcision

The second case study within this thesis evaluates the use of HES data to identify if boys undergo unnecessary surgery give the incidence of phimosis - the almost exclusive disease that circumcision is indicated for, is so well documented.

Circumcision is a relatively simple urological procedure in which the foreskin of the penis is removed. The skin of the penis is then sutured or stitched to a layer of mucosa or skin immediately adjacent to the coronal sulcus of the glans. The procedure, if performed in the paediatric population will almost always be performed under general anaesthetic.

A number of complications can occur following circumcision [Williams et al, 1993, Kaplan et al, 1983]. Early complications include haemorrhage and urinary retention..

The most common complication is thought to be postoperative infection which tends to occur between 5 and 10 days following surgery. More serious complications such as amputation of the glans and urethral fistula are exceeding rare.

2.3.2 Phimosis

Phimosis, or more accurately, pathological phimosis, is characterised by cicatrisation - narrowing of the preputial orifice, together with the histological appearance of Balanitis Xerotica Obliterans (BXO) on microscopic pathological analysis [Thomas et al, 2002]. This contrasts with, physiological phimosis, also referred to as developmental non-retractability of the foreskin, which describes the normal penile development in which preputial adhesions, located between the glans penis and the foreskin, prevent the retraction of the foreskin in young boys.

Pathological phimosis with associated histological changes of BXO is an absolute indication for circumcision where as physiological phimosis, a perfectly normal phenomena, affects all boys at the time of birth and persists to varying degrees during childhood, and therefore should not be regarded as abnormal and as such does not require circumcision [Rickwood et al, 1989].

Presentation of pathological phimosis usually takes the form of secondary, non-retractability of the foreskin following an initial period of retractability, a feature that separates it from developmental non-retractability and rarely occurs in boys less than five years of age.

The incidence of phimosis has been investigated and reported in some detail by both Shankar and Rickwood. Both found the incidence of phimosis within similar English populations was about 0.6%. Given that few other medical conditions are indicated for circumcision, if HES data suggested that more than 0.6% of the English population were undergoing circumcision, the HES database would have identified that too many boys were undergoing the procedure within the NHS.

2.3.3 Additional medical conditions that may be treated by circumcision

In addition to pathological phimosis, circumcision may also be indicated for recurrent balanoposthitis, paraphimosis and megaprepuce, all three of which are relatively rare indications for circumcision.

Recurrent balanoposthitis – is the term used to describe recurrent infections of the foreskin, as well as being rare, must occur on more than three separate occasions before a paediatric surgeon will consider foreskin surgery and furthermore, even when surgery is considered, the majority of boys undergo foreskin saving procedures such as preputioplasty as opposed to full circumcision.

Paraphimosis - a condition that occurs when the foreskin is incapable of being reduced following initial forceful retraction, is again rare in boys below 15 years of age and does occur, often simply needs reduction rather than circumcision.

Finally, megaprepuce - a congenital abnormality characterised by a large prepuce sac, is extremely rare, only being described within the medical literature relatively recently and as such is unlikely to count for a high percentage of the boys undergoing circumcision on a national basis.

2.4 Description of the Diagnosis and Treatments for Benign Prostatic Hyperplasia (BPH)

The third and fourth case studies within this thesis both concern Benign Prostatic Hyperplasia, often referred to simply as BPH.

2.4.1 Diagnosis of BPH

BPH is a chronic disease affecting the prostate, the aetiology of which is poorly understood. However, although the disease is likely to be the result of many different interactions [Wein et al, 2007, Kirby et al, 2000], the majority of theories note the importance of androgens such as testosterone in prostatic development and enlargement.

Histologically, BPH results from the formation of nodules within the prostate brought about by an increase in the number cells within the gland. These nodules lead to the disruption of the normal architecture of the prostate together with enlargement of the gland as a whole. It is this disruption of the prostatic architecture that leads to the symptoms experienced by men with the disease.

Symptoms resulting from BPH - commonly referred to as Lower Urinary Tract Symptoms or LUTS for short, can be classified as either *voiding symptoms* such as poor flow and hesitancy, or *storage symptoms* such as frequency and urgency.

Voiding symptoms are thought to relate to mechanical obstruction to the flow of urine caused by the prostate enlarging and encroaching on the urethral lumen. *Storage symptoms* on the other hand are thought to result from secondary changes within the bladder brought about by chronic obstruction of the bladder by the prostate, which results in the bladder muscle – the detrusor muscle, becoming hyperactive.

In an attempt to characterise and measure the symptoms of BPH, the American Urological Association (AUA) developed a self-administered questionnaire that was designed and validated not only to identify the need for treatment in men with LUTS secondary to BPH, but also to evaluate men once treatment had been commenced/performed [Barry et al, 1992]. This questionnaire forms the basis of assessment for men with BPH.

2.4.2 Treatments for BPH

Prior to the development of medical therapies for the treatment of BPH in the early 1990's, men would either undergo prostate surgery or be monitored with a watchful waiting policy [Wilson et al, 2004, Wasson et al, 2000].

At the current time, treatment options for men with LUTS suggestive of BPH will often depend on the AUA symptom score [Barry et al, 1992].

Men with mild symptoms will be recommended watchful waiting while men with moderate or severe symptoms will be offered medical therapy as first line treatment followed by surgery if their symptoms don't improve.

Medical therapy essentially involves the use of two different classifications of drugs, alpha-receptor antagonists and 5-alpha-reductase inhibitors.

Alpha-receptor antagonists act by initiating smooth muscle relaxation within the prostate and bladder neck that in turn reduces the impairment of urinary flow caused by BPH. 5-alpha-reductase inhibitors on the other hand result in a reduction in prostate size by blocking the conversion of testosterone to dihydrotestosterone - an androgen essential for prostatic growth.

Surgical options for men with LUTS suggestive of BPH include Transurethral Resection of the Prostate (TURP) and open simple prostatectomy.

TURP involves removal of prostatic tissue from within the prostatic urethra with the use of electrical cautery. A camera and lens system is used to enable visualisation of the prostatic urethra allowing the surgeon to remove prostatic tissue using a wire loop that cuts into the prostate removing boat-shaped chips of tissue.

Open simple prostatectomy is an open procedure by definition whereby a lower abdominal incision is fashioned to approach the prostate. Today, it is only performed in men with very large prostate glands in whom TURP would be unsafe.

By the early 1990's, 95% of men undergoing prostate surgery underwent TURP as apposed to open prostatectomy [Xia et al, 1999]. The outcome of this procedure has

been studies in detail and as such has become known as the gold standard surgical treatment for men with LUTS suggestive of BPH against which all other treatments should be considered [Wasson et al 1995, Thomas et al, 2005].

2.5 Description of the diagnosis and treatment of invasive bladder cancer

2.5.1 Diagnosis and staging of bladder cancer

Bladder cancer is estimated to be the fifth most commonly diagnosed non-cutaneous solid malignancy in Europe and the US and the second most commonly diagnosed genitourinary malignancy after prostate carcinoma [Boring et al, 1995, Cancer Research Statistics, 2000]. Bladder cancer is three times more common in men than women and more common in Caucasians as opposed to non-Caucasians.

In the western world, 90% of bladder cancers originate from the transitional cells that line the urinary tract and as a result are called Transitional Cell Carcinoma's (TCC). Alternative bladder cancers include adenocarcinoma's, Squamous Cell Carcinoma's (SCC) and small cell carcinoma's.

Haematuria –blood within the urine, is the cardinal sign of bladder cancer. Classically patients describe painless intermittent haematuria. 1 in 4 patients presenting with macroscopic haematuria – blood within the urine that the patient can visibly see, will subsequently be found to harbour a urogenital malignancy.

All patients with haematuria are required to undergo a full history and abdominal examination that should include a digital rectal examination to evaluate the prostate. All patients should provide urine for analysis (both microscopy and culture together with cytological interpretation), undergo imaging of the urinary tract e.g. renal tract ultrasound, and finally undergo flexible cystoscopy – endoscopy of the bladder.

The definitive diagnosis of a bladder cancer is made on histological analysis of a biopsy taken from the identified bladder lesion. If the bladder lesion is small to moderate in size, the whole lesion can be removed endoscopically. This procedure, performed with the patient under general anaesthetic, is known as a Transurethral

Resection of Bladder Tumour (TURBT), and is performed using a resectoscope. This piece of equipment is exactly the same as that used to perform a TURP for BPH.

Bladder tumours are “staged” according to the depth of tumour invasion into the bladder wall. Currently, bladder tumours are staged via the TNM (Tumour, Nodes, Metastases) classification system. This system allows precise and simultaneous description of primary tumour extent (T) along with the status of the lymph nodes (N) and the presence or extent of metastatic disease. Staging varies from Ta, meaning the tumour is limited to the inner lining or mucosa of the bladder, to T4 meaning the tumour has invaded into an adjacent organ beyond the bladder itself. All patients with stage T2 disease – tumour invasion into bladder muscle wall, and above are considered to have muscle invasive bladder cancer.

At the time of diagnosis, 70-75% of patients will have Ta-T1 bladder cancers, i.e. cancers that are limited to the lining of the bladder. These tumours are sometimes referred to as ‘superficial’ bladder cancers. The remaining 25-30% have muscle invasive bladder cancer.

As one might expect, bladder cancers that have invaded into the bladder wall and beyond, have a significantly worse prognosis than those limited to the lining of the bladder wall.

2.5.2 Treatment of bladder cancer

Patients found to have superficial disease can easily be treated by TURBT. However, patients with muscle invasive disease require additional treatment. Without such treatment, mean life-expectancy is approximately 2 years, much worse than superficial disease where very few patients die of their disease.

Curative treatment for patients with muscle invasive disease involves either removing the bladder surgically, known as a radical cystectomy, or radical radiotherapy, both of which may be combined with chemotherapy. To date, few studies have compared the effectiveness of surgery versus radiotherapy for muscle invasive bladder cancer.

However, a recent meta-analysis of 4 randomised controlled trials suggested a survival advantage in favour of surgery, especially for younger patients.

Radical cystectomy is performed via a mid-line abdominal incision. In the male, the bladder is removed en-bloc with the prostate and occasionally the urethra. In addition, pelvic lymph nodes are removed. In the women, an anterior pelvic clearance is performed whereby a hysterectomy, salpingo-oophrectomy and upper third vaginectomy is performed, in addition to removing the bladder.

Following removal of the bladder, urine output can be directed via a cutaneous diversion (ileal conduit) to a stoma bag for collection. Alternatively, an orthotopic or ectopic bladder can be reconstructed using the patients' bowel.

2.5.3 Determinants of outcome following radical cystectomy

There is no doubt that reviewing results of early radical cystectomy series i.e. prior to 1980, operative mortality rates were reported as high as 15-40% [Hollenbeck et al, 2007]. With improvements in operative surgical technique and post-operative care, peri-operative mortality has fallen significantly over the last 20-30 years to between 2 and 4%.

Stage of disease and lymph node status has also been found to correlate strongly with long-term outcomes namely disease specific and overall survival. Disease-specific 5-year survival can be expected to be as high as 90% in patients with pT2N0 disease. This compares with 77% for patients with pT3aN0 and 62% for those with pT3bN0. Furthermore, it has been shown that in patients with organ confined disease and more than one lymph node positive for malignant disease, 5-year specific survival falls to 54% compared to 86% in patients with organ-confined disease without lymph node involvement.

Recently, a number of studies have been reported that, at least for short-term outcomes, a surgeons or individual hospitals annual work load with regard the number of surgeries performed, impacts on patient outcome. As yet however, there is no data that explains why such an association may exist.

Section 2

The Hospital Episode Statistics (HES) database and review of the literature

Chapter 3

The Hospital Episode Statistics (HES) database

3

3.1 Introduction

The Hospital Episode Statistics (HES) database was first established in 1989. Its inception was the result of a report authored and chaired chiefly by Dame Edith Komer that concerned the predecessor of the HES database, namely the Hospital Activity Analysis (HAA). This database, established in 1970, only collected a 10% sample of all records concerning hospital admission to a National Health Service (NHS) hospital. On the other hand, the introduction of the HES database was designed not to contain data on a representative sample of hospital admissions, but to contain data on all hospital admissions. The database covers all NHS trusts in England, including acute hospitals, primary care trusts and mental health trusts. More recently, the database has included records relating to care commissioned by the NHS, but provided by independent treatment centres in England.

Data are collected and made available in data-year files running according to the financial year, i.e. from 1st April to 31st March and as such, so far data files are available from 1989-1990 to 2004-2005. From 2003 onwards, as well as collecting records on hospital admissions, data relating to outpatient attendance were also included in the database, which added a further 40 million records to the pre-existing 15 million already collected concerning admission.

Currently over 15 million records are collected each year containing data on 13 million admissions to NHS hospitals in England [www.hesonline.nhs.uk]. These records include private patient admissions in NHS hospitals but not those admissions to distinct private hospitals.

Since 1989, there have been a number of changes to the processes by which HES data is collected analysed and subsequently made available. These changes have inevitably been brought about by changes in the structure of the NHS as a whole. Initially HES data was collected on a sub-national level by individual Regional Health Authorities (RHA). However, from 1996 onwards, these bodies were disbanded and the NHS-Wide Clearing Service (NWCS) was set up to facilitate the transmitting of data files from a regional to a national level. This work will subsequently be taken over by the National Programme for IT's Secondary Uses Service in 2006.

3.2 What is the purpose of the database?

The database was initially established for use in policy development, for illustrating variations in health status and delivery with time and between geographic areas, medical research, in assessing performance, and determining the distribution of taxpayers' money on healthcare. However, recently there has been a change in emphasis with greater resources being devoted to clinical data. The current aims of the database are first, to provide a high quality service, responsive to the needs of the users of HES data including the government and medical researchers. Second, to continue adapting such that HES reflects changes in healthcare delivery. Third, to continue developing new analytical methodologies within the database. Fourth, to offer high quality, informed advice on how best to utilise HES.

3.3 What is HES an example of?

The data contained within the HES database is an example of 'routine data'. Routine data is data that is collected irrespective of the procedure or outcome. Other examples of routine data include deaths, births and stillborns, cancer registry data and statutory notifications of infectious diseases. Alternatively, data may be collected with a specific purpose in mind. Most audit and research data may be thought of as representing this form of data. This form of data is normally collected after a specific research question has been identified with the data collected relating specifically to the specific research question. Protocols would normally be generated prior to any data collection as well as data proforma's. Examples of this form of data include the National Tonsillectomy audit [Lowe et al, 2004] and the National Prostatectomy audit [Emberton et al, 1995].

Other 'routine data' sources like HES tend to arise from the administration of healthcare delivery and as such the main producers of such data tend to be national governments and insurance providers. Advantages of using routine data such as HES is that routine data are relatively cheap – given that they have already been created, they tend to be large which in turn reduces sampling error when analysing association and span significant time periods which in turn allows time-trend analysis.

3.4 Structure of the HES database

The HES database collects data in the form of Finished Consultant Episodes or FCE's. A FCE is defined as a completed period of care that a patient has received under a single named consultant. FCE's were initially introduced to measure resource use within the NHS. An FCE is initiated or commenced when either a patient is admitted to hospital or if a patient's care is taken over by another named consultant while remaining in hospital. In contrast, an FCE is terminated either when a patient's period of care is completed and the patient is discharged from hospital, or when a patient care is transferred to another named consultant. In this way, a single FCE does not always correspond to a single admission, nor does each separate FCE correspond to a different patient. As a result, each FCE is numbered according to its sequential occurrence during a patients' hospital admission, this is subsequently referred to as the EPIORDER. Data concerning the EPIORDER of each FCE is collected and documented within each FCE.

A spell is defined as a patients' entire stay in hospital. A spell is terminated in any one of three ways. First, the patient dies during the hospital admission second, the patient is discharged from hospital or third, the patient is transferred to another hospital. As such, a spell may consist of several different episodes of care or FCE's. However, as mentioned above, HES data is not, in its raw form, packaged or collected in spells. Instead, the data needs to be manipulated and analysed by linking episodes of care (FCE's) so as to view data of admission or spell level.

Counting FCE's as well as spells is not the same as counting individual patients. A patient that is unwell may have multiple FCE's relating to more than one spell during a particular year and as such, if FCE's or spells were considered and counted as separate individuals, this would lead to patients being counted more than once, so-called double counting. In such a way, use of FCE's or spells as numerators to calculate incidence of disease is likely to lead to over-estimation of disease incidence.

In an attempt to make HES data more useful for clinical research, the Department of Health in England introduced from 1997 onwards, patient specific identification

numbers called HESID numbers. Within each FCE, there is from 1997 onwards, a data field in which each patient's HESID is documented. This number is unique to each patient and is generated from a patient's NHS number. When a new FCE is generated, a search is done using a HESID matching algorithm to determine if the patient has a previous HES database history i.e. a search to detect activity records that relate to the same patient. This matching algorithm involved two steps. The first step involves attempts to match records using the variables SEX, DOB (Date Of Birth) and Hospital Number. If this step fails to identify a matching FCE, attempts are made to match according to SEX, DOB, Postcode and Local Patient Identifier within Provider – a local patient identifier number. If the FCE is matched to a previously existing record, the record assumes the HESID already established for that patient, if no pre-existing record is identified, that a new HESID identifier is generated.

Once HESID was introduced, patients could be identified across multiple database years and as such allowed for the identification of patient as opposed to episode level data.

Data is collected within HES according to HES datayears. Each datayear starts on the 1st April and ends on the 31st March – a period that equates to the financial year. As a result, studies that utilise HES data, especially those that report on trends over time, will often report trends between these dates.

3.5 How HES data is collected

Healthcare providers such as the NHS trusts collect administrative and clinical information locally. Data are collected from medical records following the discharge of the patient from hospital. The process of data collection is summarised below.

1. Documentation in the medical record of all diagnoses made and procedures undertaken by the doctor.
2. Transfer of the medical record to the coding office following patient discharge from a clinical area by hospital management.

3. Dates of inpatient spell and FCE identified using NHS data definitions by the coder.
4. Identification of relevant diagnoses and procedures from the medical record by the coder.
5. Coding of primary diagnoses and procedures from the medical record by the coder.
6. Returns sent to NHS-Wide Clearing Service (NWCS) by hospital management.
7. Data aggregated and analysed by the department of Health.

As mentioned above, data returns are submitted at regular intervals throughout the year to the NHS-Wide Clearing Service (NWCS). However, as of December 2006, the NWCS is due to be taken over by the Secondary Users Service (SUS) as part of the National Programme for IT. Currently the NWCS then forwards the data to the Health care commissioners but also copies the data to a separate database. At pre-arranged times throughout the year, the NWCS takes an extract of their collected data and sends it to Hospital Episode Statistics database. HES then verifies, cleans and validates the extract, derives new items and then makes the data available within the so-called HES Data Warehouse. Initial verification is the process by which the HES database reviews each record to ensure that it contains a minimum amount of data. Minimum data requirements for each record include data regarding hospital provider, type of hospital admission as well as date of admission and date of termination of each episode such that the record can be incorporated within a specific HES datayear.

The process of data cleaning or autocleaning on the other hand involves not only identifying that data is present within each data field but that all coded data as well as recorded admission and termination of episode dates are valid i.e. they are in the correct format for the database. In addition, autocleaning involves the reclassifying or overwriting of invalid codes and dates with “unknown” indicators. HES also checks for anomalies within the data, e.g. reviewing the recorded sex within HES for those

who have given birth. HES will either correct the code if there is sufficient evidence that the code can accurately be corrected or overwrites the code again as “unknown” if this is not possible. On occasion, HES may identify that a particular NHS provider consistently uses an incorrect provider code. If this is the case, then the particular code is changed within HES providing the provider is in agreement.

Finally, validation refers to the process by which individual records are tested against a set of rules with the aim of identifying errors that may remain following the autocleaning process. Following this a report is generated that summarises the quality of the submission from the data provider. This report contains a target data quality threshold that acts as a benchmark against which data providers can assess their performance.

The HES service is run on behalf of the Department of Health of England by Northgate Information Solutions.

3.6 Data collected within the HES database

As alluded to above, data concerning an episode of care is recorded in a data record called an FCE that in turn is divided up into a number of data fields. These data fields include basic demographic and administrative data, details regarding a patient's method of admission to hospital, clinical data referring to the admission including operative and diagnostic details and details of hospital discharge. In addition, the specified consultant that the patient is primarily assigned to will be documented according to a specific number that in turn is derived from the practitioner's general medical council number. Many of these items are generated automatically by the Patient Administration Systems (PAS) that are present within all NHS hospitals in England although the HES database does generate specific data such as the patient's age, identified from PAS detailed date of birth.

The HES database stores clinical data in the form of alphanumeric codes. Prior to April 1995, diagnoses were recorded with HES according to the ninth revision of the International Classification of Diseases coding system (ICD-9), thereafter, the tenth revision of the International Classification of Diseases coding system was used (ICD-

10) [WHO, 1994]. This coding system was generated by the World Health Organisation (WHO) and is maintained and published by this organisation. The ICD-10 classification of diseases is the latest in a series of disease classifications that were formalised in 1893 as the Bertillon Classification or International List of Causes of Death.

Within the database, from 2002 onwards, there are 14 diagnoses fields, each of which has space for a single ICD-10 diagnosis code. These data fields are labelled DIAG_1-14, meaning diagnosis field 1-14. These diagnosis fields are further labelled primary diagnosis – i.e. the main complaint that the patient experienced for that particular episode of care, secondary diagnosis, tertiary diagnosis etc. Thus it is possible to report up to 14 different medical conditions that the patient may currently have or have previously experienced. Prior to 2002, there were only 7 diagnosis fields (labelled DIAG_1-7). Diagnosis codes commence with a letter and thereafter are followed by two or three digits. For example:

N47	Phimosis	Q54	Hypospadias
R33	Urinary Retention	N40	Benign Prostatic Hyperplasia

Over the last decade there has been a shift towards identifying additional secondary diagnoses within the HES database. This is supported by a recent study by the Department of Health that identified that twice as many secondary diagnoses were recorded for the HES datayear 2003-2004 (20 million) compared to 1993-1994.

Operations are recorded within the HES data according to the 4th revision of the Offices of Populations Censuses and Surveys operative procedure coding system (OPCS-4) [OPCS, 4th revision, 1987]. The OPCS-4 coding system has evolved from a series of classifications initially published by the Medical Research Council (MRC) in 1944. Several updates have been performed to the latest 4th revision, in 1987, 1988 and 1989. The classification is maintained and published by the NHS information Authority. Up until the HES datayear 2002-2003, there were 4 operative fields within the HES database, each of which has space for a single OPCS-4 operative code. These data fields are labelled OPER_1-4, meaning operation field 1-4. However, from 2002-2003 onwards, in a similar manner to diagnosis coding, the number of operative fields

increased to 12 (OPER_1-12). These operative fields are labelled primary procedure/intervention, secondary procedure/intervention onwards. Although the primary procedure may not be the main procedure performed during that episode of care, it should be the ‘most resource intense’. This in effect makes the primary procedure the main procedure performed in the majority of patients. In addition, each operative field is associated with another data field labelled the date of primary or secondary etc operative procedure. These ‘date of operative procedure’ fields tend to be recorded in chronological order and as such, occasionally if patients have a minor procedure e.g. a prostate biopsy, and then undergo radical prostatectomy, the prostate biopsy can be recorded as the primary operative procedure with the prostatectomy being recorded as a secondary procedure. This highlights the need to evaluate all operative field codes when searching for surgical procedures that a particular patient may have undergone.

The OPCS-4 coding system consists of a tabular list of 23 anatomically based chapters relating to a body system. Each chapter, concerning a particular body system, is allocated an alphabetic character that forms the first digit of the code, for example M denotes urinary tract. Subsequent numbers included within the operative procedure code record the particular procedure performed on that body system. For example:

N303	Circumcision	M65	Transurethral Resection of the Prostate
M731	Repair of Hypospadias	M34	Cystectomy

3.7 Coding accuracy

The quality of data - be it routinely collected or primary data, will be dependant on how complete the data are as well as how accurate the data are. While one of the key strengths of the HES database is its size and completeness, there are concerns with regard the accuracy of HES data and this will always be the case providing validation of HES data continues to be performed on a national as opposed to a local level. These concerns inevitably relate to the accuracy of coding, especially diagnosis and operative procedure coding, within the database. In response to these concerns, especially given that use of routine data such as HES was increasingly being utilised by both UK government policy makers as well as medical researchers, Campbell and

colleagues [2001] recently performed a systematic review of both diagnostic and operative discharge coding accuracy within routine UK hospital statistics. This review identified 21 studies, published between 1996 and 1998, that had investigated the accuracy of coding within routinely collected hospital episode data. Accuracy was defined as the proportion of hospital episode records that have the same code as that assigned by an independent review of the discharge summary or medical record. The review found that median coding accuracy rates for diagnoses ranged from between 82 and 91% depending on whether the data originated from England and Wales or Scotland and between 70 and 97% for operative procedures. The authors concluded that coding accuracy on average is high in the UK, especially for operations and procedures.

There is also evidence that coding accuracy within the HES database is improving further. For example, Hansell and colleagues – reporting on patients undergoing varicose vein operations in a single region of England, identified, after comparing HES data records with diagnoses and operative procedures identified following medical note review that the accuracy of coding within HES had increased between 1989 and 1995 with 98% accuracy being found for the last year of the study.

While it has been argued that the accuracy of coding within UK routine data sources was inferior to that of the US, UK routine data such as HES is more likely to be free of ‘code creep’ than their US counterparts. Code creep – the deliberate and systematic shift in a hospitals reported case-mix, achieved by using additional diagnostic codes, so as to improve financial reimbursement, although previously demonstrated to exist in routine medical databases such as Medicare in the US, is less likely to be a confounding factor within HES as reimbursement is not linked in same way to hospital reimbursement as it is in the US [Lezzoni et al, 1997]].

Linkage with death records from the Office of National Statistics (ONS)

Where a patient dies in hospital, this is clearly documented within the database. From this it is possible to report in-hospital mortality. One important issue identified from the Bristol inquiry into outcomes of paediatric cardiac surgery at the city hospital was that there were no procedures in place at the time to ensure systematic follow-up of patients following surgery. In particular, there was no data on 30-day mortality

after surgery. This was especially important as all statistical analysis done for the Bristol inquiry was based on 30-day mortality outcomes as opposed to in-hospital mortality. In response, Murray and colleagues [Murray et al, 2002] developed a methodology by which HES data records could be linked to death records taken from the Office of National Statistics (ONS) mortality statistics. In such a way, 30-day mortality could be reported.

The validation study by Murray et al of HES record linkage to national mortality statistics was performed and published in June 2000. Their methodology was based of that used in Scotland for many years to link the Scottish equivalent of HES data – the Scottish morbidity records, to Scottish national mortality records.

Linkage of records is essentially based on a technique of probability matching which translates the level of agreement and disagreement between each item of identifying information contained within 2 records. Identifying information would include data such as Date of Birth, Sex and Postcode as these variables are present both within the mortality records held by the Office for National Statistics as well as the HES database.

Murray and colleagues concluded in their HES/ONS linkage exercise that linkage was highly feasible. In specific regard to the Bristol inquiry, the authors concluded that simply reporting in-hospital mortality as opposed to 30-day mortality resulted in 8.4% of 30-day deaths not recorded. They further concluded that it should become routine practice within the Health Service in England and Wales to link HES data records with Office for National Statistics mortality records [www.bristol-inquiry.org.uk]. Further work by Aylin and colleagues [Aylin et al, 2001], again investigating the value of HES data linked to mortality records reached a similar consensus.

In response, the Department of Health in England has agreed to link such records and as such data within the HES warehouse is now indeed matched with death records taken from the Office of National Statistics (ONS) mortality statistics as a matter of course [www.doh.gov.uk/hes].

3.8 The Emerging uses of HES data

The Introduction of Payment by Results

In 2002, the Department of Health in England announced a new system of financial remuneration for NHS hospitals which was named Payment by Results (PbR) [Department of Health: Reforming NHS financial flow, 2002].

Traditionally, hospitals developed contracts with their local primary care trusts – organisations legally established whose purpose it is to develop health services for a particular community, in which they would receive an agreed financial sum to provide a certain amount of clinical activity. Block contracts were often developed whereby the hospital in question would agree to provide a particular service for an agreed period of time, often without specifying the volume of activity that such a service provision would require. For example, a hospital might agree to perform all hip replacements deemed clinically necessary for a certain period of time.

In contrast to block contracts, under PbR, hospitals are paid essentially on a case per case basis. This policy is facilitated by treatments and procedures being assigned to a “Healthcare Resource Grouping” [Farrar et al, 2009]. HRG’s represent health care activities that are clinically similar and require similar levels of resources. Prices for activities in each HRG’s are then set by the DOH and detailed in a national tariff. In 2005, PbR was brought in to cover nearly all medical and surgical specialities in England.

Since the introduction of the PbR policy, HES data has taken on vital importance as the policy is essentially administered by the HES database with hospitals only gaining financial reward for the clinical activity identified to have been undertaken at their institution according to their HES data returns.

The impact of PbR on the quality of HES data is yet to be known, however it is suggested that the quality of HES data may potentially improve as hospitals realise that if data submitted to the NHS-Wide Clearing Service (NWCS) is not accurate, they will lose out financially [www.abdn.ac.uk/heru]. In addition, there is the possibility that HES data will suffer from “code creep” whereby multiple codes are increasingly used to gain maximum financial gain for the hospital, the effect of which

is to distort disease burden which in turn can influence the ability of researchers to accurately account for co-morbidity confounding [Lezzonni et al].

The increasing use of HES data to generate Hospital Standardised Mortality Ratio's and Dr Foster Intelligence

Hospital Standardised Mortality Ratio's (HSMR) were devised by Professor Jarman and the Dr Foster Unit at the Imperial College of Science and Technology in London [Jarman et al, 2005]. It has been suggested that HSMRs can represent a measure of quality within healthcare provision. HSMRs act to identify if the death rate at a hospital is higher or lower than expected [Aylin et al, 2009].

HSMR's are unable to identify specific failings in healthcare but may be used to identify areas where more investigation is required. HSMR's are calculated by dividing the observed number of deaths within a hospital by the expected number of deaths multiplied conventionally by 100 i.e if the mortality is higher in the population being studied than expected, the HSMR will be greater than 100. The expected number of events or deaths is calculated by evaluating data on all patients undergoing the procedure or admission across the country, i.e. a comparison with the national average. Adjustment can subsequently be made for age, gender, method of admission and socio-economic deprivation.

The Dr Foster Unit is an independent organisation which collects and analyses information on healthcare services in the UK. The unit is headed by Professor Jarman and Dr Aylin. The Dr Foster Unit has developed a number of so-called quality indicators, one of which is HSMR's [www.drfoosterintelligence.co.uk]. HES data is used by Dr Foster to generate many of their quality indicators including HSMR's.

Dr Foster has access to HES data which it uses to publish its HSMR's which are documented within its yearly Dr Foster Hospital Guide. HES data is used by Dr Foster to identify the number of observed events for each hospital which it then divides by the expected number of events generated by its analysis of average outcomes across the UK, again derived from its analysis of HES data.

Dr Foster analysis and publication of HSMR's has been used to benchmark practice in the UK and has identified marked failings in the quality of healthcare provided by several hospitals in England. One high profile case involved the Mid Staffordshire hospital trust which Dr Foster identified as having significantly higher mortality ratios than expected for a 3-year period between 2003 and 2006 [www.drfosterintelligence.co.uk]. The Healthcare Commission was alerted and a report conducted into the quality of care provided at the hospital demonstrating the value of HES data to monitor the quality of care across NHS hospitals.

3.9 Accessing HES data and Confidentiality issues

Access to HES data can be achieved in one of two ways [Hansell et al, 2001]. First, an application can be made to the HES database to acquire a HES data extract for a specific period of time. A HES extract specification form must be completed which details the data years required e.g. 1989/90 to 2001/2002, the filter details e.g. identify all FCE's in which surgical repair of hypospadias was performed (OPER_1-4=M731) as well as the fields to be extracted. These fields would normally include date of admission (ADMIDATE), method of admission (ADMIMETH), method of discharge (DISMETH), date of birth (DOB), episode duration (EPIDUR), date of episode end (EPIEND), episode order (EPIORDER), sex (SEX) as well as many others (see appendix 1).

Alternatively, HES data extracts can be accessed via the online HES Interrogation System. Using a software computer system called Business Objects, the HES database can be accessed directly by the researchers institution allowing the researcher to build a HES data extract query which can subsequently be downloaded via secure internet connection to the researchers base computer from the HES database.

Business Objects essentially acts to translate a query in **Standard Business Terms** into **SQL** which is then submitted directly to the HES database.

To gain either access to HES online via the online HES Interrogation System or to gain a HES extract via application, the HES applicant or prospective HES user must sign the HES protocol that states that the user as well as the users institution satisfies

the necessary system security requirements as well as stating that the user has paid the stated fee (£2,842 annual charge for 2003-2004) as well as the licence fee. In addition, approval of the Security and Confidentiality Advisory Group is required before any data is accessed. Finally, if online access is sought, the user must attend a specific training course to be taught how to use the Business Objects software computer package.

Accessing HES data for this thesis

HES data analysed within this thesis was acquired in two separate ways. First, an application was made to the HES database by completing a HES Extract Pack application form. This form stated that I – Paul Cathcart, was the Data Custodian. The HES Extract Specification Form (appendix one) requested a data extract for the HES datayears 1995/1996 through to 2003/2004. Filter details included all FCE's in which it was identified that a circumcision (OPCS-4 code –N33) had been performed (OPER_1-OPER_4). We requested all subsequent episodes of care over a period of 2 years following the initial surgery. This was requested so that we could identify any complications arising from surgery that were sufficiently severe to warrant hospital readmission. Amongst others, requested data fields included all diagnoses (DIAG_1 to DIAG_14), all operations (OPER_1 to OPER_4), admission date (ADMIDATE), treatment speciality (MAINSPEF) and date of birth (DOB) such that patient age could be calculated.

To collect a HES data extract concerning Hypospadias surgery, transurethral prostatectomy and acute urinary retention, a query was generated using the Business Objects software programme which was submitted to the online HES Interrogation System. The 3 separate queries (appendix two, three and four) were submitted to the online HES Interrogation System for the HES datayears 1989/1990 through to 2003/2004. As each HES datayear is managed as a separate *Universe* – logical grouping of classes within Business Objects corresponding to an individual datayear within the HES database, a separate query submission was constructed and submitted so as to download a HES data extract for each HES datayear. As a consequence, to extract HES data for each procedure between 1989/1990 through to 2003/2004, 15 identical queries were required to be submitted to the online system.

Due in part because the online submission and query-generation process was a detailed process, and because all users of the HES database should undergo training with regard HES database confidentiality, I – Paul Cathcart, attended The Information Centre for Health and Social Care's (The IC) authorised training course. As part of this 4 day course, held and organised by Northgate systems HQ in Hertfordshire, I received training in the use of Business Objects. In addition I was required to sign the HES Protocol, stating that I would comply by the HES defined security requirements.

Finally, the HES data extract used to investigate the impact of delay prior to radical cystectomy as well as the investigation of how higher volume hospitals achieve improved outcome following radical cystectomy, was again acquired by submitting an application to the HES database for all records relating to hospital admissions in which urological cancer procedures took place. However, this HES abstract, relating to patients undergoing surgery in England between 1995/1996 and 2001/2002 and including all records concerning admissions in the year before and after surgery, was originally applied for by my predecessor – Mr Martin Nuttall, and as such he is the named Data Custodian. His application is illustrated in appendix . However, although he has previously analysed this HES data abstract, it was not for the purpose described in this thesis. Furthermore, although he acquired this dataset, I performed a further HES data extract request concerning all recorded deaths for those patients identified to have undergone radical cystectomy between 1995/1996 and 2001/2002 and subsequently linked all *index records* – FCE in which surgery took place, with all death records obtained from the Office of National Statistics (ONS) via the HES database.

3.10 Costs of utilising HES data over other national audit data

The increasing demand for improvement in the quality of care within the NHS has resulted in the increasing need to collect and report data on clinical outcomes – especially surgical outcomes which represent measures of clinical effectiveness.

However, the creation and upkeep of clinical databases is considered expensive which is why it is argued that HES data may be able to provide a cost effective alternative.

This argument is reinforced by a recent review of costs of individual clinical databases by Raftery and colleagues [Raftery et al, 2005]. This review identified that use of HES data could save between £9 and £60 pounds per patient record collected depending on which clinical database HES was compared to. The review estimated that the cost of each individual HES record was £1 compared to £10 pounds to each record within the UK cardiac surgical register and £60 for each patient record created within the Scottish Hip fracture audit database. Clearly if HES could be used instead of generating individual clinical datasets, the cost of monitoring and improving the quality of care in the NHS could be substantially reduced.

Chapter 4

Use of HES data to study incidence, surgical treatments and their outcomes: A review of the literature

4.1 Introduction

An essential component of the NHS modernisation agenda is the need for quality improvement of surgical services [Cancer Services: Improving outcomes]. For improvement to occur within all three recognised domains of quality, namely – effectiveness of care, patient safety and patient experience, better collection and monitoring of data concerning existing services is required [High Quality Care for All: NHS Next Stage Review Final Report. www.dh.gov.uk/en/Publicationsandstatistics]. As such, complete, timely and accurate data is required.

In response the Care Quality Commission, formerly the HealthCare Commission and before that the Commission for Health Improvement (CHI) has commissioned several large national audits such as the National Tonsillectomy Audit [Lowe et al, 2004] to collect data on the effectiveness of patient care – one of the three aspects of healthcare quality. However, such audits have proved to be expensive, labour-intensive and time consuming [Measuring and Using outcomes of Surgery: www.rcseng.ac.uk]. Furthermore, they will only ever be able to investigate and report on a narrow select number of surgical procedures and interventions.

In the US, a similar desire for accurate surgical outcomes data to reflect effectiveness of surgical care has led researchers to look towards administrative data such as the Medicare database. A number of researchers have utilised such data to evaluate outcomes of surgical activity on a large population-based scale to considerable success. The advantages of administrative data are that they are relatively cheap to utilise as they already exist and therefore data does not need be collected, they tend to be large which enables studies utilising such data to be amply powered as well as reducing the chance of sampling error while data will often span a number of years which will enable trends over time to be elucidated [Lauderdale et al, 1993, Bright et al, 1989]. Limitations of such data are likely to stem from concerns over their accuracy, as clinicians have not been involved in the collection process.

Alike outcomes data, data concerning disease occurrence within society are also known to be lacking. Those data that are available are often based on small sample-based studies, the results of which have been extrapolated to the general population to

give disease burden estimates. Such methodology has many limitations and as a result, the validity of such data has been brought into question. An alternative approach is to conduct population-based studies where all cases of a particular disease within the population are identified. However, such studies have tended to be expensive and labour-intensive. As a consequence, only a limited number have been performed. HES data may be considered a source of population-based data and as such potentially has the capacity to be used to identify disease incidence in England.

In this thesis, the HES database is evaluated as a source of data to answer specific clinical questions regarding first, the incidence of urological disease and second, the processes and outcomes of urological surgery. However, before these analyses are commenced, this chapter reviews the literature to identify to what extent the HES database has previously been used for both these purposes.

In addition, when available, data concerning the *accuracy* of HES to report on both disease incidence and outcomes of surgical activity, when compared to local information systems such as clinician audit data, was also sought. Finally, the purpose of using HES data to perform the study was also evaluated.

4.2 Methods

The following electronic databases were searched: Medline (1st January 1966-1st January 2006), Embase (1980-2003), the Health Management Information Consortium and the Cochrane library. The searches were performed using both key words and MeSH headings (see Appendix 6). The reference lists of all articles of all identified articles were hand searched for other relevant studies and electronic searches were performed using the names of key authors who were known to have published widely in this field.

Inclusion criteria to identify studies utilising the Hospital Episode Statistics database to report on the incidence of surgical conditions

Studies were included if they utilised HES data to report incidence on the one hand and surgical conditions on the other. Studies were excluded if the majority of the data report on was not HES data. For example, a number of studies by Goldacre and

colleagues, published on behalf of the Oxford Record Linkage (ORL) study group have not been included in this review as although they do use HES data to report on incidence of surgically treatable disease, for the most part, the data utilised in these studies pre-dates the existence of HES data. For example, Goldacre and colleagues have reported incidence of cancer after cholecystectomy using HES data extracts for the Oxford NIIS region, however, only data from 1989 onwards was HES data, while the majority of data reported on in this study – 1963-1989, was generated from Hospital Inpatient Enquiry records which were the predecessors of HES data records.

Inclusion criteria to identify studies utilising the Hospital Episode Statistics database to report on outcomes of surgery

Studies were included if they utilised HES data to report health related outcome on the one hand and surgical procedures on the other. Studies were excluded if the majority of the data reported on was not HES data. For example, a study by Filipovic and colleagues, reporting mortality after Abdominal Aortic Aneurysm (AAA) repair has not been included in this review as although HES data is used to report on outcome of AAA repair between 1989 and 1999 in English hospitals, for the most part, the data utilised in the study (1979-1989) predates the existence of the HES database.

In addition, studies were also excluded from the review if they report outcome of a surgical condition rather than specifically reporting outcome of surgery, even if that surgical condition would almost inevitably ultimately require surgery. For example, a study by Goldacre and colleagues, reporting 30-day, 90-day and 180-day mortality following fractured neck of femur, is excluded from this review as, although it identifies outcome of patients who almost always require surgery, a small proportion of the patients included in the study would not have undergone surgery and as such, it does not strictly report on the outcome of a surgical procedure.

Two reviewers assessed the retrieved articles for inclusion and exclusion criteria. The same reviewers extracted data from included articles. Any disagreement in study inclusion or data extraction was resolved by a third reviewer.

Data extraction from studies reporting on the incidence of surgical conditions

Data extracted from each study was divided into three sections. The first section included data on study characteristics and included first author name, year of publication, surgical procedure or surgical condition being reported on as well as the time period over which the data was collected. The second section, referred to as the methodological section, included data extracted on whether 'patient level' or 'hospital admission/episode level' statistics were analysed, whether trends over time were reported on and whether HES data was compared with a local information system. If comparison was made with a local data system, the accuracy of HES data to report incidence was recorded. Accuracy was designated as high, intermediate or low. An accuracy category was assigned by each of the two reviewers. Any disagreement was, again resolved by a third reviewer. The third section included data concerning the purpose of the study. Studies were considered either to have been performed for health needs assessment, understanding of disease aetiology or assessment of new technology introduction. The studies were grouped in chronological order by date of publication and summarised in tabular form.

Data extraction from studies reporting on outcomes of surgery

Data extracted from each study was divided into four sections. First, data were extracted from each study on authors name, year of publication, surgical procedure, outcome reported on, whether the study reported descriptive outcomes of a particular procedure – categorised as a descriptive study, or if the study identified the determinants of outcome of a procedure – categorised as an analytical study.

Second, data were extracted on whether adjustment was made for confounding factors when analysing the determinants of surgical outcome such as patient age, patient co-morbidity and disease status. Each study included in the review was assigned a score that corresponded to the degree of adjustment accounted within the study when reporting on outcomes of surgery. A score of 0 indicated no adjustment, a score of 1 indicated adjustment for demographic variables only while a score of 2 indicated adjustment for demographic variables together with co-morbidities. A score of 3 indicated adjustment for demographic variables, co-morbidities and disease severity.

Third, data was collected on whether the HES reported outcomes were compared with those identified from local information systems. If comparison was made with a local data system, the accuracy of HES data to report health related outcomes of surgery was recorded. Accuracy was designated as high, intermediate or low. An accuracy category was assigned by each of the two reviewers. The studies were grouped in chronological order by date of publication and summarised in tabular form.

Fourth, data was extracted on the purpose of the study. Studies were considered either to have been performed for benchmarking of surgical standards in England, patient safety, healthcare-needs assessment or finally for the evaluation of the accuracy of the HES database to report surgical outcomes. The studies were grouped in chronological order by date of publication and summarised in tabular form.

Patient level versus admission/episode level of care

Studies that utilise HES data to report either incidence of disease or outcome of surgery may report their results either on an individual patient level, on an admission level or on an episode level. This is because HES data is collected in *units of completed consultant care* called “FCE’s”, as opposed to collecting data on an individual patient basis (see introduction to the HES database). In this review, we investigate to what extent individual studies attempt to account for FCE’s when reporting either incidence of surgical disease or outcome of surgical activity.

4.3 Results

4.3.1 Incidence of surgical conditions

Included studies

Overall, 20 articles were included in the review (see table 4.1). 6 studies were identified as having utilised HES data to report the incidence of orthopaedic conditions, 7 on general surgical conditions, 2 on oral surgical conditions, 1 a vascular condition, 1 a urological condition and finally 1 article reported on the incidence of a gynaecological condition. 2 further studies reported incidence of multiple surgical conditions, irrespective of surgical speciality.

Coding

12 studies utilised the UK Tabular List of the Classification of Surgical Operations and Procedures Version 4 of the UK Offices of Populations, Censuses and Surveys (OPCS-4) to report incidence of surgical procedures while 8 utilised the International Classification of Diseases coding system to identify incidence of disease diagnoses.

Time periods & locality reported on

The earliest article to utilise HES data to report incidence of a surgical condition was published in 1996, after which the annual number of publications utilising HES data remained steady at approximately 2 (0-3) articles per year up until 2006, the last year included in this review. The majority of studies (11/20) utilise HES data to report trends over time in the incidence of surgical conditions.

The majority of studies (17/20) included HES data before 1997 (the year in which HESid numbers were introduced) while only 2 reported incidence estimates exclusively using data after this date. Regional HES data records were utilised by 7 studies as opposed to utilising national HES data files.

Unit of reported incidence

The majority of studies (14) utilised age-standardized rates as their unit of incidence, while 4 studies reported annual rates only and 1 study reported a cumulative incidence rate. In this study, the incidence of paediatric femoral fracture was calculated by dividing the number of finished first consultant episodes for all children aged up to 16 years of age by the mid-year population estimate for the number of children living in the area for which HES data was collected (denominator, West Midlands).

In addition, 1 study reported standardized operation ratio's by dividing the number of surgical procedures performed in a specific primary care trust region of England by the population estimate for that region and then dividing this fraction by that identified for other English primary care trusts. In this way, variation in surgical activity for specific surgical conditions across healthcare boundaries was reported on which in turn suggested inequalities of access to surgical services across England.

Accuracy of HES data

Only 2 studies compared HES data findings with other data systems. In the first study, Ferris and colleagues interviewed vascular surgeons practicing in hospitals located within the Wessex Regional Health Authority to identify if the number of carotid endarterectomies identified to have performed within the region between 1991 and 1996 according to HES was correct. The study concluded that there was minimal underascertainment by HES as the surgeons confirmed the approximate number of operations. The second study, by Gupta and colleagues, compared the incidence of pneumothorax identified within HES with the General Practice Research Database (GPRD). This study reported an incidence of pneumothorax of 24.0 per 100,000 per year generated from the GPRD compared to 16.7 for the HES database. However, although these figures appear slightly different, it was acknowledged that the HES database would only identify those patients that required hospital admission whereas the GPRD would have identified milder cases that may have been managed in the primary care setting only. On average, accuracy of HES data to identify incidence was assessed as moderate or high.

Numerator used to calculate Incidence

10 of the 20 articles included in the review report incidence using the FCE as the *numerator* value when calculating the incidence of the particular surgical condition while 6 studies identified the first episode of an admission spell (see introduction to the HES database) as the numerator while 4 studies utilised a combination of date of birth, postcode, discharge destination in combination with the episode order to identify individual patient level numerator values. McColl and colleagues identified that using a combination of episode order as well as date of birth and length of stay, the use of FCE's as opposed to patient level data, overestimated incidence by 17%. Furthermore, the study suggested that when this methodology was applied across regions, the degree of overestimation varied from 1% to 56%. Ferris and colleagues, utilising a similar methodology, reported that over ascertainment by using FCE's as opposed to patient level data overestimated incidence by 11.3% (30 duplicates out of 266). Pollock and colleagues, again reporting on variation between use of FCE's to report incidence compared to patient level data, identified using linkage methodology using a combination of postcode, date of episode start, and patient identifiers postcode, date of birth and sex, that FCE's over estimated incidence by between 5%

and 8%. They report this difference as a ratio 1.05-1.08. No study identified within this review however, reported use of HESid to identify patient level data.

Purpose of studies included in review

The vast majority of studies (19/20) identified within this review were commissioned for Health needs assessment purposes as opposed to the identification of aetiology or the assessment of technology introduction. 3 studies identified inequality in surgical services, both for the availability of orthopaedic and bariatric as well as oral surgery services, while 2 studies utilised HES data to champion centralisation of specific surgical services. 3 studies reported on or hypothesised about disease aetiology. The first study compared the incidence of salivary duct calculi across the different regions of England with the hardness of tap water in these regions in an attempt to investigate the hypothesis that hard water leads to an increasing incidence of the disease. The second study, utilised HES data to identify that the incidence of pancreatitis in England was rising and then in turn linked this finding with data from the General Household Survey that suggested alcohol consumption in England was rising. The last study, reported incidence and cause of paediatric femoral fractures utilising HES data to suggest maltreatment was less frequent a cause than previously thought.

6 studies reported on how the introduction of new medical technologies have impacted on the incidence of surgical conditions. For example, Kang and colleagues reported that the use of surgery for cholelithiasis i.e. cholecystectomy and biliary duct exploration has fallen while the use of new therapeutic techniques for treating gallstones (e.g. ERCP) has increased. This trend at the same time had coincided with an increase in the admission rate for cholelithiasis suggesting that either the incidence of the disease was rising or that endoscopic procedures were less efficacious than surgery. Another example of how HES has been used to report the impact of new technology is demonstrated by Oliver and colleagues in their paper entitled, “the epidemiology of diffusion”. In this study, the incidence of radical prostatectomy for the treatment of localised prostate cancer can be seen to have increased 20 fold in England since 1991, a trend that mirrored the increasing incidence of localised prostate cancer that resulted from the introduction of widespread Prostate Specific Antigen (PSA) testing during this time.

Methodological Limitations

All but 1 study included in this review reported limitations associated with the use of HES data. These limitations included, lack of data on patients undergoing surgery in the private sector, the use of FCE's as opposed to patient level data, questions over HES data completeness as well as issues over accuracy of coding of both diagnoses and operative procedures. Arguments to counter these limitations included, the finding that less than 5% of patients in England have private health insurance, that 95% of admissions identified in the HES database have a single episode recorded, that studies conducted by the Department of Health suggest coverage of HES to be consistently high – for example, 98% completeness in 1989-90 and 102% completeness (because of extra submissions from a single RHA) in 1991, and that a number of studies have consistently reported the accuracy of ICD-10 and OPSC-4 coding within the HES database was high (between 75% and 97% accurate).

4.3.2 Outcomes of surgery

Included studies

Overall, 21 articles were included in the review (see table 4.2). 5 reporting on outcomes following general surgical procedures, 4 reporting vascular procedures, 4 cardiac procedures, 4 urological, 1 gynaecological, 1 orthopaedic and ear nose and throat surgeries and 1 reporting on multiple surgeries of different specialities.

9 studies were descriptive in nature, reporting national outcomes of upper and lower bowel surgery, aortic aneurysm repair, coronary artery bypass surgery, paediatric cardiac surgery, radical nephrectomy and radical cystectomy, while 12 were analytical papers reporting on the determinants of outcome for oesophagectomy, cholecystectomy, laparoscopic appendectomy, radical prostatectomy, carotid endarterectomy, radical cystectomy as well as paediatric cardiac surgery (3) and tonsillectomy.

Time Period

3 articles were published before 2004 (2001, 2001 and 2003), the rest thereafter with the majority (18) being published in 2005 (2007 – 5 papers, 2008 – 4 papers) a trend that demonstrates the increasing use of, and interest in, HES data to report surgical outcomes in England.

Outcomes

15 of the 21 articles used in-hospital mortality as their primary outcome measure, 5 of which further define the outcome to in-hospital mortality within 30 days of admission.

Only 1 of the 21 articles identified in the review explicitly report in their studies methodology section that FCE's were linked such that outcomes may be reported on a patient level. 3 studies report using the FCE as the reporting unit, while the remaining 5 articles do not mention if analyses are based on an episode, admission or patient basis. However, 1 study was designed such that FCE's were the unit of interest rather than individual patients and as such FCE's were not used as a proxy for individual patients.

Several other outcome measures were analysed. Clark and colleagues scanned all operative fields within the HES database to identify all patients undergoing tonsillectomy who had the additional operative OPSC-4 code "F36.5" which specifically describes "surgical arrest of post-tonsillectomy bleeding". Using this single code, this article suggested that adults were at higher risk of post-operative bleeding than children. Harley and colleagues developed a much more elaborate and comprehensive method by which the HES database could be used to identify outcome of surgery. In this study, 7 performance measures or outcomes were identified. The first measure or outcome was the percentage of FCE's with a coded complication. Complications were identified by scanning all diagnostic fields of patients undergoing gynaecological procedures for ICD-9 codes 996-999 and ICD-10 codes T80-T88 indicating "complications of surgical and medical care not elsewhere classified". In addition, outcome was evaluated by reporting the mean length of a spell, the percentage of FCE's with more than one operation, the percentage of FCE's where a spell was longer than an episode, the percentage of FCE's for dilatation and curettage, the percentage of FCE's for sterilization in patients under 25 years of age and finally the percentage of FCE's for hysterectomy on women under 30 years of age.

Adjustment

8 of the 12 analytical papers adjusted for confounding in their analyses of determinants of surgical outcome. Aylin and colleagues, reporting on the outcome of

paediatric cardiac surgery between 1991 and 2002 - a study designed to evaluate the impact of the Bristol inquiry, adjusted for the different cardiac procedures performed by each of the 11 paediatric cardiac centre included in their analyses. Given that different cardiac procedures have different risks of in-hospital death, this clearly important when analysing outcome from each centre. Furthermore, although the authors did not adjust within their analyses for age, they did perform separate analyses for patients above and below 1 year of age, the effect of which was age adjustment. Furthermore, although specific co-morbidity was not separately adjusted for, given that patients included were under 1 year of age, their co-morbidity status would have been inferred by the particular surgical procedure they underwent as it would be unlikely they had an additional medical problem other than their primary cardiac one.

The second article by Aylin and colleagues included in this review again reports on outcome of paediatric cardiac surgery. However in this study, the authors adjusted for patient age at the time of operation, the proportion of patients with Downs syndrome (i.e. to some degree adjustment is made for co-morbidity), the proportion of transfers from other units as well as the proportion of patients admitted as an emergency.

The article by Spiegelhalter and colleagues, again using HES data to investigate the determinants of outcome of paediatric cardiac surgery, also attempted to adjust for patient related factors when performing their analyses, on this occasion including type of cardiac procedure when investigating the impact of centre volume on outcome.

A final article by Aylin and colleagues, on this occasion evaluating the accuracy of HES data to predict death following surgery compared to national clinical databases, also attempted to make adjust for confounding in their analyses. On this occasion, secondary diagnostic fields were utilised to create comorbidity variables which were then categories according to the Charlson Index of comorbidities.

Comparison with other data sources and accuracy of HES

6 studies in total compared HES data with alternative data sources. Both Aylin and Spiegelhalter compared HES with the UK Cardiac Surgical Register (CSR). Aylin and colleagues report that HES identified 99% of in-hospital deaths compared to CSR data although if deaths outside hospital were included it identified a slightly lower

percentage at 92%. Furthermore, despite this slight underascertainment, the authors found that HES was able to identify that Bristol was an outlier with regard in-hospital 30-day mortality in those under 1 year undergoing open cardiac surgery and as such, would have identified that the Bristol Royal Infirmary required investigation for its excess mortality rate. Spiegelhalter, again comparing HES with the CSR, found both identified that higher volume centres had better outcomes with regard in-hospital 30-day mortality and again found both HES and the CSR could have been used to identify the excess cardiac mortality in Bristol.

Westby and colleagues in their 2007 BMJ paper compared the HES database with the Central Cardiac Audit Database (CCAD). The primary outcome measure of the study was the comparison of the data sources with specific respect to capture of 30 day mortality after paediatric heart surgery in those children under 1 year of age. The study found that HES data omitted between 5% and 38% of infants operated on in each centre. It also identified a median 40% shortfall in the number of deaths occurring following surgery. The study went on to state that 30-day mortality according to HES data was 4% compared to 8% as identified by the CCAD. The study concluded that HES data was unsatisfactory for the reporting of individual units outcomes following paediatric cardiac surgery.

In a similar vein, Pandey and colleagues utilised HES data to report hospital standardised mortality ratios (SMR) and compared those gained from HES data with those calculated from a single centres internal clinical database. The study found that HES data identified 115 of 223 aortic procedures undertaken at the unit. Furthermore, the study calculated that the SMR calculated for the institution using HES data was 160 compared to 67 when their own internal clinical database was used. The study concluded that HES data may be misleading.

In contrast, 2 more recent studies have suggested HES data has moderate to high accuracy when compared to local clinical data sources. In the first, Garout and colleagues compared caseload and mortality following colorectal cancer surgeries identified using HES with that recorded in the Association of Coloproctology of Great Britain and Ireland (ACPGBI) colorectal cancer database. The study identified that HES identified 12% more procedures than the clinical database with overall

reasonable agreement for national caseload as well as mortality reporting. It was noted that individual hospital reporting however was poor.

In the last study that compared HES data with clinical audit data, Aylin et al compared the ability of HES data to predict death following surgery with that derived from national clinical databases including the National Cardiac surgical database, the national vascular database and the colorectal cancer study database. The study identified that HES data could be used to predict risk of death with similar discrimination to that of clinical databases (ROC curve score 0.77 versus 0.78 for CABG procedures, 0.80 versus 0.78 for colorectal excision surgeries).

Purpose of studies included in review

10 of the 21 studies identified within this review were commissioned for the purpose of evaluating and reporting national outcomes of surgery, the effect of which is the utilisation of HES data to benchmark surgical practice in England. 7 of the 21 studies were commissioned to report on healthcare needs assessment in England, the majority of which reported that outcomes of several different surgeries are improved if performed in higher volume centres, the overall message being that services should be centralised.

4 of the 21 studies included within this review were commissioned for the purpose of assessing the accuracy of HES data when compared to local or national audit data. Information concerning these studies is the subject of the prior section.

2 of the 21 papers identified within this review were commissioned to evaluate the use of the HES database to report on issues of patient safety – one of the 3 aspects of quality, in England. In the first, by Raleigh and colleagues, investigated if HES data could be utilised, with the use of ICD-10 diagnosis codes, to identify a number of patient safety indicators. The study concluded that HES data does have the potential for monitoring safety events. The second study reporting on use of HES for patient safety purposes found that HES could be used to identify geographic areas where there was excess mortality following aortic surgery suggesting HES could be used not only to benchmark outcomes but also identify outliers.

Methodological limitations

All but 1 study included in this review reported limitations associated with the use of HES data. Aylin and colleagues report that HES has problems with data quality but state that the “crucial issue is not whether the data are correct, since they manifestly contain errors, but whether such errors are likely to be great enough to mask the underlying pattern in the data”. It happened that the extent of the Bristol mortality was such that HES was able to identify it as an outlier. In such a way, the ability of HES to identify outliers will depend the how much of an outlier they are. Michaels and colleagues also raise the issue of coding irregularities as a limitation of HES. To address this, the authors aggregated codes for different procedures, sub-divided patients according to whether they underwent elective or emergency surgery and excluded younger patients, as they were likely to have different disease parameters.

4.4 Discussion

Summary

This review demonstrates HES data has been utilised to report incidence of surgical disease over time. In addition, the review identified that of those studies that have utilised HES data to report incidence of surgical disease, the majority used the Finished Consultant Episode (FCE's) as the numerator while only 20% of studies attempted to identify patient level data. In turn, use of FCE's was identified to over-estimate incidence of surgical conditions by as much as 17%. No studies to date were found to have utilised HESid to identify patient level data when evaluating incidence of surgical disease. Age-standardized incidence rates were the most commonly used unit of incidence although cumulative incidence and age-standardized ratios were described. Furthermore, although few validation studies had been performed, comparing HES incidence estimates with those generated from local information systems, those that have, suggest HES data accuracy was either moderate or high. Finally, the majority of studies identified in this review to report incidence of surgical conditions were performed with the purpose of informing health needs assessment.

This review also identified that HES data has been used to describe and investigate the determinants of outcome of surgical activity. Although in-hospital mortality was found to be the most commonly studied surgical outcome, authors appear to have developed alternative outcome measures by screening diagnostic and operative fields for codes suggesting adverse events or second surgical procedures. Studies utilising HES data to report outcomes of surgical activity have also utilised demographic, admission, diagnostic and procedural information to adjust, at least in part, for case-mix when analysing outcomes of surgery. The review identified that HES data are increasingly being used to report national outcomes that in turn allows benchmarking of effectiveness of surgery in England – one aspect of quality. In addition, studies are being to be commissioned to look at how HES data may be used to identify patient safety as well as benchmark practice, both of which are likely to lead to improvement in quality of surgical services in the UK. Finally, there appears to be an ongoing debate concerning the accuracy of HES data to report outcomes of surgery with some arguing its use is appropriate whereas others have strongly suggested HES data can

lead to inappropriate conclusions. However, more recent studies have suggested the accuracy of HES data to predict outcome of surgery is similar to clinical datasets.

Methodological limitations of the review

This review, like all reviews, suffers from the limitation of publication bias. This is nowhere more appreciable than when analysing the reported accuracy of HES data for studies that utilise HES data to report their conclusions are likely to report high levels of ascertainment and as such a high level of accuracy when comparing their data with local data systems, as if this were not so, the paper is unlikely to have been published. By the same token, studies that utilised HES data to report incidence of surgical disease, which subsequently found their data to be inaccurate, are unlikely to have been accepted for publication. A further limitation of this review again concerns our ability to make strong conclusions with regard the accuracy of HES data. We found only 8 out of a possible 41 studies that compared their HES data with local data systems and those that did reported conflicted findings. As such, our ability to make strong conclusions on the accuracy of HES data to report incidence of surgical conditions is hampered.

Clinical Implications

The findings of this review suggest that the HES database can, and is, able to be used to report the incidence and changing incidence of surgical conditions in England. However, our finding that, despite the availability of HES data, only 2 papers on average are published each year using HES data for this purpose, suggests that the database is currently an under-utilised resource.

However, our review does suggest that straightforward use of the database, for example, by means of FCE's as the numerator unit of incidence, leads to biased estimates of incidence. A finding that is in keeping with other studies that have reported on the utilization of routinely collected administrative data in monitoring incidence of disease. As such, our study implies HES data should not be used indiscriminately to report incidence, rather that data be analysed using data-sensitive methodological solutions.

Although the review found that use of HES data to report individual surgeons outcomes can be misleading, the finding that HES data appears to be as accurate as clinical datasets to predict outcome of surgery suggests that HES data can be used to describe and investigate the determinants of outcome of surgical activity.

This review also found that outcomes measures, other than in-hospital mortality, may be developed within the confines of the HES database, either by developing novel strategies to search and identify diagnostic and operative coding or by aggregating diagnosis and operative codes that in turn would enable the database to be more useful. This is especially so when using the HES database to analyse outcomes of a surgical procedure where in-hospital death is a rare event. In such cases, the development of alternative, more commonly occurring outcomes, such as post-operative bleeding for example, would allow for more appropriate data interpretation and as such allows the database to be more useful both for research purposes as well as the continued monitoring of the quality of delivered healthcare.

One commonly quoted limitation of the use of administrative data to report on outcomes of surgical care is that adjustment for case-mix is essential when interpreting and analysing outcome. This has led to resistance by clinicians to use HES data and other administrative data sources alike. This review identifies that, although adjustment will never be complete within the HES database, appropriate statistical methods can be utilised whereby adjustment for case-mix can at least be partly accounted for. Furthermore, while authors to date have adjusted for particular surgical procedures as well as specific medical diagnoses, this review suggests that this methodology could be further extended such that a co-morbidity score, generated from diagnostic and operative codes identified within the diagnostic and procedure fields of each patient's HES record, could be developed which in turn could be used to adjust more fully for case-mix when analysing and comparing outcomes of surgery.

Lastly, our finding that those studies that have reported on the accuracy of HES data to report outcomes of surgery do report conflicting results does suggest future research should include further work to establish the accuracy of HES data.

Conclusions

The HES database has been used to identify both trends in the incidence of surgical diseases as well as surgical outcomes reporting. The review highlights that care needs to be taken when analysing HES data for purpose of incidence reporting as incidence estimates are sensitive to data handling. On the other hand, the HES database would appear to offer exciting opportunities for the reporting of disease incidence together with the investigation of health-related surgical outcomes provided appropriate statistical analysis and methods are applied.

Table 4.1 Studies reporting Incidence of surgical conditions using HES data

1 st author Year Published	Procedure	Condition	Period	Methodology			Purpose of study						
				Patient level Level	Admission / Episode FCE	Trends over Time	Incidence	Comparison with alternative Data source	Accuracy*	Health needs Assessment	Aetiology	Impact of Technology	Conclusions
Dixon 2006	Hip & Knee	N/R	2000	-	•	-	Age-standardized rates	-	-	•	-	-	Inequality in joint Replacement surgery provision –Regional
Aylin 2005 Procedures	10	N/R	2003	-	•	-	Standardized operation ratios	-	-	•	-	-	Regional variation in surgical provision
Wilkinson 2005	Bariatric Surgery	N/R	1996-2002	-	•	•	Annual Rates	-	-	•	-	•	Access to obesity surgery variable, Need for centralisation
Dixon 2004	Hip & Knee Replacement	N/R	2000	-	•	-	age-standardized rates	-	-	•	-	-	Inequality in joint surgery provision– socio-economic
Bridgman 2004	-	Femoral Fractures Children	1991-2002	•”	-	•	Cumulative Annual rate 0-15	-	-	•	•	-	Decreasing incidence of paediatric fractures Few for maltreatment
Kang 2003	-	Diverticulitis	1989-2002	•”	-	•	Age-standardized	-	-	•	-	-	Increasing Admission rates

							rates						for Diverticular disease
Kang 2003	Appendectomy	Appendicitis	1989-1990 1999-2000	•"	-	•	Age-standardized rates	-	-	•	-	-	Decreasing incidence of altered Gen.Surg. workload
Kang 2003	Cholecyst-Ectomy	Biliary colic	1989-1999 1999-2000	-	•	•	Age-standardizes rates	-	-	•	-	-	Gallstones increasing increasing use of Endoscopic treatment
Oliver 2002	Radical Prostatectomy	Prostate cancer	1991-1999	-	•	•	age-standardized rates by region	-	-	•	-	•	increasing use of surgery need for centralisation
Tinto 2002	-	Pancreatitis	1989-1990 1999-2000	•"	-	•	Age-standardized rates	-	-	•	•	-	incidence increasing with increasing alcohol use
Higham 2002	Vagotomy Partial Gastrectomy	Peptic Ulcer	1989-1999	-	•	•	age-standardizes rates	-	-	•	-	•	Decreasing DU incidence and DU surgery with introd. of medical therapy
Balasegaram 2001	-	Hip fractures	1989-1990	•"	-	•	age-standardized rates	-	-	•	-	-	incidence stabilising
Sherman 2000	-	salivary Calculi	1991-1994	-	•	-	Annual rates	-	-	-	•	-	salivary calculi are not associated with hard water

Gupta 2000 thorax	-	Pneumo-	1991-1994	•	-	-	•	-	-	report single incidence est.
Ferris 1998	carotid End- arterectomy	N/R	1991-1996	•	-	•	•	-	•	insufficient use of surgery compared to incidence of disease
McColl 1998	-	Hip fracture	1993-1995	•	-	-	•	-	-	Incidence rising HES data can be used, after Adjustment for multiple admissions
Gilthorpe 1997	oral surgery	-	1989-1994	-	•	-	•	-	-	use of oral surgery influenced by socio-
Economic status										
Pollock 1997 Cancers	-	Colorectal	1989-1993	•	-	•	•	-	•	stable incidence of disease
Mulholland 1996	Hysterectomy	N/R	1990-1993	-	•	-	•	-	•	despite advantages of vaginal approach, few Perform the procedure
Chenet 1996	-	Multiple	1994	•	-	-	•	-	-	HES data, after analysis can be effectively used hospitalisation influenced by socio-economic status

N/R= not research i.e. diagnosis codes not utilised to report incidence, H=high, M=moderate L=low, ** = Carotid endarterectomy, haemorrhoidectomy, cholecystectomy, tonsillectomy, prostatectomy, CABG, Hysterectomy, Hip replacement, appendectomy, Hernia repair

**NOF= Fractured Neck of Femur, * = Patient level data identified using first episode of care as a proxy, '-'=Patient level data identified using HES/id or alternative methodology i.e. report identification of duplicates

Table 4.2 Studies reporting on outcome of surgery that have utilised the Hospital Episode Statistics database

1 st author Year Published	Procedure	Descriptive/ Analytical	Outcome	Adjustment				Score	Comparison with alternative data source	Accuracy*	Conclusions
				Demo- graphics	Co- morbidity	Disease Status					
Leigh 2009	oesophagectomy	A	in-hospital Mortality	•	-	-		1	-	-	high vol hospitals improved outcome
Ballal 2009	Cholecystectomy	A	Conversion Rates	•	-	•		1	-	-	high vol decreases conversion rates
Faiz 2009	Lap. Appendectomy	A	mortality	•	-	-		1	-	-	lap appendectomy is safe
Garout 2008	Bowel surgery	D	30-day mortality	-	-	-		0	•	M	reasonable agreement Between HES and clinical datasets
Pal 2008	upper GI surgery	D	in-hospital Mortality	-	-	-		0	-	-	High vol hospitals improved outcomes
Raleigh 2008	Hip fracture	A	9 safety indicators In-hospital mortality Los	-	-	-		0	-	-	HES data can be used to gain info on safety events
Holt 2008	AAA	D	in-hospital Mortality	-	-	-		0	-	-	HES can be used to benchm AAA repair
Judge 2007	radical Prostatectomy	A	in-hospital mortality, los Complications	•	-	-		1	-	-	High vol hospitals have improved outcomes
Holt 2007	carotid	A	in-hospital	-	-	-		0	-	-	high vol improved outcome

Endarectomy		mortality, los complications							
Pandey 2007	AAA repair	D	-	-	-	0	•	M	inaccuracy of SMR reporting
Aylin 2007	CABG/AAA Bowel surgery	D	•	•	-	2	•	H	accuracy of HES data predicts to predict outcome as good as clinical datasets
Westby 2007	Congenital heart Surgery	D	-	-	-	0	•	L	HES data unsatisfactory for outcomes reporting
McCabe 2005	Racial Cystectomy	A	-	-	-	0	-	-	higher volume centres have improved outcome
Nuttall 2005	Radical Nephrectomy	D	-	-	-	0	-	-	annual number of nephrectomies increasing in England
Harley 2005	All gynaecological Surgeries	A	-	-	-	0	-	-	HES able to identify bad practice (Rodney Ledward)
Nuttall 2005	Radical Cystectomy	D	-	-	-	0	-	-	no centralisation of radical cystectomy services
Clark 2004	Tonsillectomy	A	-	-	-	0	-	-	adults more likely to bleed after tonsillectomy
Aylin 2004	Paediatric cardiac surgeries	A	-	-	••	1	-	-	since Bristol inquiry, mortality in Bristol fallen
Michaels 2003	Aortic surgery	D	-	-	-	0	-	-	variation in centre mortality rates, grouping of ICD-10 & OPSC codes helpful
Aylin 2001	Paediatric cardiac Surgeries	A	•	•	••	3	•	H	Bristol was an outlier HES data is accurate in reporting outcomes
Spiegelhalter 2001	Paediatric cardiac Surgeries	A	-	-	•	1	•	H	higher volume centres have improved outcome

H=high, I=intermediate L=low, ♦ = 7 indicator variables - % FCE's with complications (diagnosis codes only), Mean length of spell, % FCE's with more than one operation, % of FCE's where a spell is longer than an episode, % FCE's for dilation and curettage, % FCE's for sterilization under 25 yrs, % FCE's for hysterectomy on women <30 yrs, ♦ adjustment for procedure, ♦ adjustment for Downs syndrome only

Section 3

Case Studies

Use of the Hospital Episode Statistics database to answer questions concerning the incidence of urological disease

Chapter 5

Is the incidence of hypospadias rising in England?

Use of HES to comment on trends in the incidence of hypospadias based on treatment of the condition compared to registry data on incidence of congenital anomalies

5.1 Introduction

Hypospadias, incomplete development of the male urethra, is one of the most common congenital malformations, the aetiology of which remains unknown [Thomas et al, 2002].

A number of studies have investigated the incidence of this anomaly, with reported estimates ranging from 0.37 to 41 per 10,000 infants [Chambers et al, 1999, Nelson et al 2005]. While the incidence of hypospadias appears to be geographically influenced, considerable variability in incidence has been reported for individual countries. This inconsistency in reported incidence is thought to be due to variation in case ascertainment as well as differences in the inclusion and exclusion criteria employed by different authors.

The importance of accurate surveillance data for this anomaly has been highlighted by several recent studies that have suggested the incidence of hypospadias may be rising. Paulozzi and coworkers were amongst the first to report on such a trend. In their study, using data from two separate US birth surveillance registries, the incidence of hypospadias was found to have increased from 2 per 1000 in 1970 to nearly 4 per 1000 in 1990. Since then, this trend has been reciprocated in several countries including Scandinavia where the incidence of hypospadias has reportedly increased from about 7 per 1000 to over 15 per 1000 since the 1970's [Aho et al, 2000].

Much debate has been had over why the incidence of hypospadias may be increasing. Some have argued that the rate of change in the incidence of hypopadias points towards an environmental, as opposed to a genetic aetiology [Vrijheid et al, 2003, Gallentine et al, 2001]. A number of environmental compounds, including various drugs, tobacco, alcohol and pesticides, have all been found to have oestrogen-like effects. Furthermore, laboratory studies using animal have suggested that these compounds are able to disrupt endocrine and reproductive systems. As such, increasing environmental exposure to these chemicals may be responsible for the reported changes in incidence of hypospadias.

In England and Wales, epidemiological surveillance of congenital anomalies is the remit of the National Congenital Anomaly System (NCAS) [www.ncas.ac.uk]. Using this data, the incidence of hypospadias in England and Wales would appear to have increased from 1.5 per 1000 male births in 1964 to 3.6 by 1984.

However, a recent validation study has questioned the accuracy of the NCAS data for epidemiological surveillance purposes [Dolk et al, 2005]. In this study, completed by a European Surveillance of Congenital Anomalies working group, only 25% of eligible cases of hypospadias were identified to have been captured within the NCAS database while 16% of registered cases were found to have been incorrectly notified [http://www.eurocat.ulster.ac.uk]. Furthermore, the introduction of new guidelines concerning the exclusion of ‘minor’ forms of hypospadias within the NCAS database was found to have resulted in marked changes in the incidence of reported hypospadias which further raised concerns with regard the applicability of NCAS data to be used for surveillance purposes.

In response, we developed a programme of work to evaluate the feasibility and validity of using Hospital Episode Statistics data on the frequency of corrective hypospadias surgery to report on trends over time in the incidence of hypospadias in England.

5.2 Methods

We considered HES records related to admissions that occurred between 1 April 1997 and 31 March 2005. This time period was chosen because a unique patient identifier was introduced in April 1997, on the basis of which it is possible to link HES records that belong to the same patient. The HES database is structured in reporting years running from the 1st April to the 31st March. We report results from 1997/1998 to 2004/2005 (subsequently referred to as 1997 to 2004).

Identification of index record

We used a three-stage selection procedure. First, we identified all HES records with an ICD-10 code indicating “*hypospadias*” (Q54) in any of the diagnosis fields. Second, we filtered these records to identify all records containing an OPCS-4 code

indicating “*repair of hypospadias*” (M731) in any of the operative procedure fields. Finally, so as to identify the index record and so prevent double-counting of patients undergoing more than one corrective hypospadias procedure, we selectively identified all records relating to the first hospital admission in which corrective hypospadias surgery was performed.

Incidence of hypospadias

Incidence estimates of corrective hypospadias surgery were established by two different analyses.

In the first analysis, a retrospective cohort study was performed using HES data to calculate an incidence estimate for corrective hypospadias surgery in 1997 - the first year in which it was possible to link HES records belonging to the same patient.

The year of birth was established for all boys undergoing corrective hypospadias surgery between 1997 and 2004 using data concerning patient age held within the age field (labelled STARTAGE) of the index labelled HES record. We then divided the number of boys, identified as having been born in 1997 (numerator), by the total number of male births in England for that year (300,689), as estimated by the UK Office for National Statistics.

Using this methodology, we were able to calculate the proportion of boys, born in 1997, who had undergone corrective hypospadias surgery within 8 years of birth. This equates to the cumulative incidence of corrective hypospadias surgery over the 8-year study period.

In the second analysis, the proportion of boys undergoing corrective hypospadias surgery by their 9th birthday was used as a proxy for the cumulative incidence of corrective hypospadias surgery. To calculate this cumulative incidence estimate, we first calculated the *annual rate of corrective hypospadias surgery* for each year reported on within the study. This was achieved by dividing the number of boys who underwent corrective surgery in that year (numerator), by the mid-year estimate of the number of boys aged between zero and 8 years living in England according to the UK Office for National Statistics (denominator) [www.statistics.gov.uk]. The proportion

of boys who would undergo corrective hypospadias surgery by their 9th birthday was then established by multiplying the *annual rate of corrective hypospadias surgery* for boys aged between zero and 8 years by 9. Calculated cumulative incidence estimates generated in this fashion assumes the observed *annual rate of corrective hypospadias surgery* for each reporting year would remain unchanged.

We then compared the cumulative incidence estimates generated by these two different methodologies.

Trends in incidence of hypospadias

It was not possible to comment on temporal trends in corrective hypospadias surgery using the retrospective cohort study design (analysis one) as every subsequent year would have one year less follow-up which would bias any results on incidence.

Instead we only utilised data on cumulative incidence estimates generated from our second analysis when commenting on trends over time in the incidence of corrective hypospadias surgery. In addition, we assumed all incidence estimates generated were Poisson-distributed counts. Poisson regression was then used to analyse trends over time.

All p values were two sided, and those less than 0.05 were judged to indicate a statistically significant result. Stata software (version 8) was used for all statistical calculations.

5.3 Results

Age at which surgical correction of hypospadias was performed is presented in Figure 5.1.

Over the 8-year study period, the median age at time of surgical correction of hypospadias was 2 years and nearly 85% (84.1%) of boys included in the study had undergone surgery by four years of age. Median age at time of surgical correction fell from 2 in 1997 to 1 in 2004 (mean age in 1997 – 2.4 years, versus 1.8 years in 2004).

Furthermore, the proportion of boys undergoing surgical correction by their fourth birthday increased from 78.0% in 1997 to 88.4% in 2004.

Incidence of hypospadias

Between 1997 and 2004, 12,458 boys aged less than 9 years were admitted to NHS hospitals in England and underwent corrective hypospadias surgery. 1,549 boys, identified as having been born in 1997, underwent hypospadias surgery by the last year of the study (2004), i.e. within 8 years of birth. This corresponds to a cumulative incidence estimate of 5.15 per 1000 male births.

1,641 boys, aged less than 9 years, were identified to have undergone corrective hypospadias surgery in 1997. Using this figure, the *annual rate of corrective hypospadias surgery* for 1997 was observed to be 0.56 per 1000 boys per year. The proportion of boys who would undergo corrective hypospadias surgery by their 9th birthday if this *annual rate of corrective hypospadias surgery* would remain unchanged it would therefore be 5.09 per 1000.

Trends in the cumulative incidence of corrective hypospadias surgery

Over the 8-year study period, the proportion of boys undergoing corrective hypospadias surgery by their 9th birthday, i.e. the cumulative incidence of corrective hypospadias surgery, increased significantly from 5.09 per 1000 boys in 1997 to 5.51 per 1000 boys in 2004 (Table 5.1, Figure 5.2).

5.4 Discussion

Summary

Incidence estimates of corrective hypospadias surgery generated in this study from HES data records are more than three times higher than the incidence of hypospadias reported over a similar period by NCAS – the national congenital anomaly register. Furthermore, this difference appears compatible with the estimated under-ascertainment to NCAS. The comparability of cumulative incidence estimates generated from use of *annual rates of surgery* with that calculated from the retrospective cohort study suggests *annual rates of surgery* could be used to report on trends over time and as such suggests HES data could be used to monitor the

incidence of this congenital anomaly over time. Finally, this study provides some evidence to support the hypothesis that the incidence of hypospadias may be rising.

Methodological limitations

There are a number of limitations associated with the use of administrative data for epidemiological purposes. First, there are concerns over the accuracy of administrative data to identify boys undergoing corrective hypospadias surgery. However, it is unlikely that coding accuracy has been a major source of error in this study as there is only a single specific OPCS-4 code for corrective hypospadias surgery as well as a single ICD-10 diagnosis code for diagnosis of hypospadias.

Second, boys undergoing more than a single-stage correction hypospadias surgery are at risk of being double-counted and as such, incidence estimates generated from this analysis may be artificially high. Again this is unlikely to have been a major source of error in this study as we specifically only used HES data from April 1997 onwards after which a unique patient identifier was introduced that enabled the identification of index records i.e. the admission during which the first corrective hypospadias surgical procedure was performed.

Third, interpretation of trends in incidence of corrective hypospadias surgery as a proxy for the incidence of hypospadias assumes first, that all boys with hypospadias undergo surgical correction and second, that the surgical management of hypospadias has not changed. Addressing the first issue, while the reporting of corrective hypospadias surgery for this anomaly will naturally represent an under-estimate of the true incidence of this condition, providing any increase in the incidence of hypospadias is not limited to those cases not managed by corrective surgery, and providing that there has been no systematic change in the use of corrective surgery, the frequency of surgical correction may be considered a reliable surrogate marker for its incidence.

As mentioned earlier, the increase in incidence of hypospadias identified in this study could reflect change in the surgical management of the condition rather than a true increasing trend in disease incidence. This is unlikely to be a major source of bias as first, there is no evidence to support such a hypothesis and second, there is evidence

on the contrary from the US that the use of surgery for the correction of hypospadias has changed little over the last 20 years [Choi et al, 2001].

Furthermore, even if our data reflected change in practice rather than true incidence, it still provides valuable information that may be utilised for health assessment purposes and the planning of treatment provision.

Comparison with other studies reporting incidence of hypospadias

Our mean cumulative incidence estimate for corrective hypospadias surgery generated from our retrospective cohort data for 1997 of 5.15 per 1000 boys as well as our mean cumulative incidence estimate of 5.19 per 1000 boys generated from *annual rates of surgery* over the entire 8-year study period compares well with the findings of a recent US study reporting on the incidence of hypospadias during the 1990's [Nelson et al, 2005]. This study, based on data from the National Inpatient Sample, utilised ICD-9 diagnosis codes to identify an overall incidence of 5.7 per 1000 boys between 1988 and 2000. Furthermore, the study reported an increasing trend in the incidence of congenital penile anomalies – including micropenis and epispadias together with hypospadias, with incidence rising from 7.0 per 1000 in 1998 to 8.3 per 1000, in 2000, a trend mirrored by our data.

Our mean incidence estimates are more than three times higher than the incidence of hypospadias reported over a similar period by NCAS (1.8 per 1000 births) while they are also not dissimilar from that reported in a recent UK study using data from the Avon region of England in which incidence of hypospadias was reported to be 6.4 per 1000 births (51/7,928) [Gallentine et al, 2001].

However, our mean incidence estimates as well as our temporal trend analysis is at odds with a recent Finnish study reporting on Finish hospital Discharge data between 1970 and 1994 [Aho et al, 2001]. In this study, the mean incidence of hypospadias, generated by utilisation of ICD-8 codes to identify those boys undergoing corrective hypospadias surgery by 8 years of age, appeared to be significantly lower than our estimates of incidence (2.8 per 1000 boys), while incidence appeared to remain stable over time. While this may reflect geographical differences in exposure to endocrine-

disrupting chemicals, it may equally reflect difference in management of boys with mild hypospadias.

Clinical Implications

It is of clear importance that surveillance of congenital anomalies be performed first, to look for associations between the occurrence of that anomaly and potential environmental teratogens, second, to support health service planning and third, to monitor prenatal diagnosis and screening programmes. These objectives apply not only to hypospadias, but also for all congenital anomalies.

It is already known that ascertainment to the national register for England and Wales (NCAS) is poor while at the same time, being highly labour intensive and as such expensive to administer and implement. Furthermore, NCAS ascertainment accuracy is expected to decrease yet further with the introduction of '*NHS numbers for babies*' – a new electronic babies record that only permits tick box information to be recorded as opposed to text data.

This study suggests that use of measures such as *annual rates of surgery*, generated from routinely collected HES data, to calculate cumulative incidence, may represent a more representative and certainly more economic alternative to NCAS data for the surveillance of congenital anomalies in England.

Conclusions

Until the problems of ascertainment to NCAS are addressed, analysis of HES data to report *annual rates of corrective hypospadias surgery* appears to represent a useful resource to monitor the incidence of hypospadias in England.

5.5 Tables

**Table 5.1: Incidence of corrective hypospadias surgery
between 1997 and 2004 in England**

Year	Cases	Rate ¹	Surgical correction of hypospadias by 8 years (per 1000) ²
1997	1,641	0.56	5.09
1998	1,600	0.55	4.98
1999	1,496	0.55	4.94
2000	1,484	0.55	4.98
2001	1,447	0.55	4.95
2002	1,633	0.63	5.65
2003	1,577	0.61	5.50
2004	1,573	0.61	5.51
P value for trend			<0.001

¹ *annual rates of surgery* per 1000 boys per year

² Proportion of boys who would have undergone corrective hypospadias surgery by their 8th birthday
if the rate of surgical correction remained unchanged (e.g. 1997 = 0.0056 X 8 = 5.09 per 1000 or 1 in every 200 boys)

5.6 Figures

Figure 5.1: Age at which corrective hypospadias surgery performed

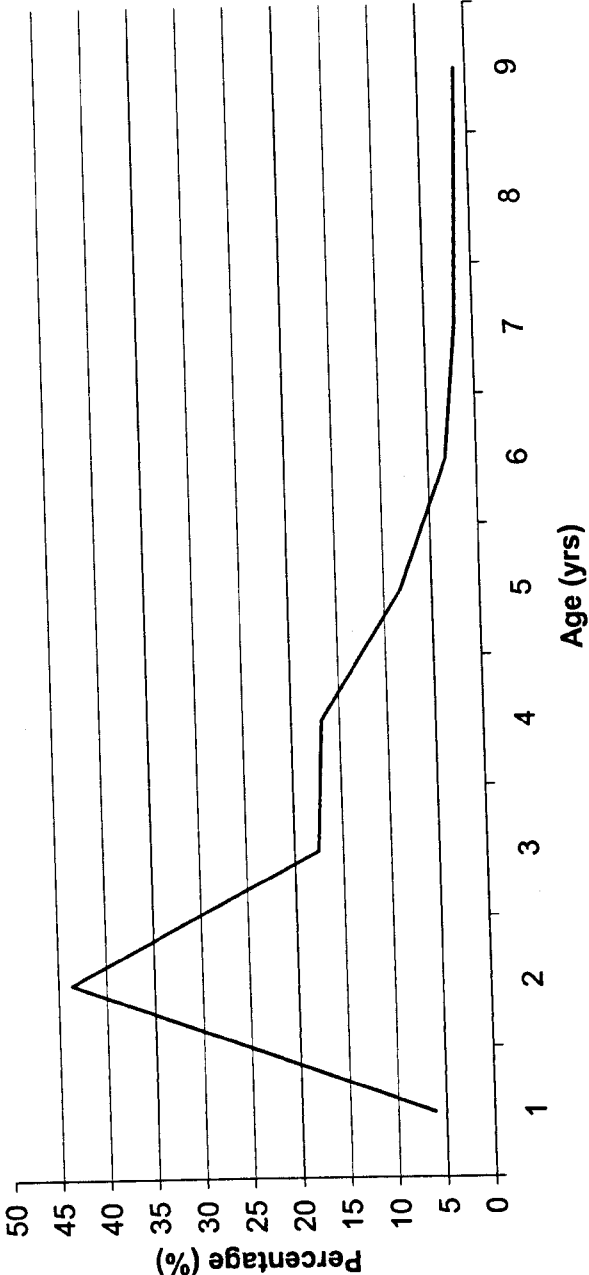
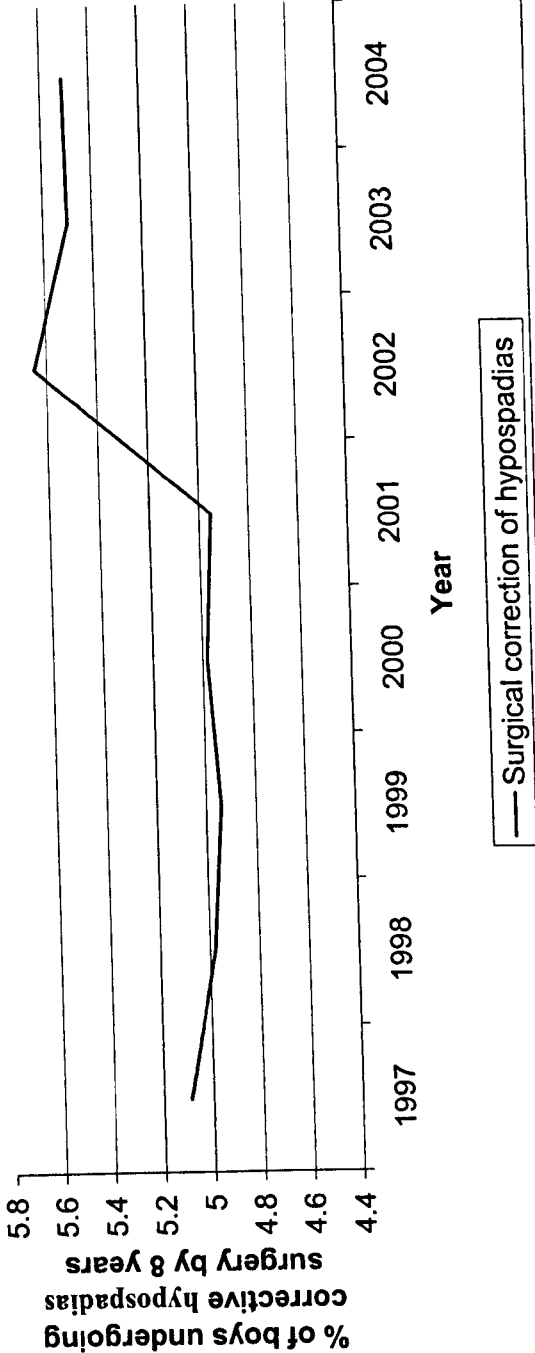


Figure 5.2: Incidence of corrective hypospadias surgery in England



Chapter 6

Are too many boys undergoing circumcision for phimosis of the foreskin in England?

Use of HES data to identify clinical appropriateness of treatment

6.1 Introduction

Circumcision is a common paediatric surgical procedure. The proportion of boys circumcised during childhood varies markedly by country, by religion and to some extent, by socio-economic group [Dewan P et al, 1996]. The proportion of men circumcised for religious reasons, in either the US or Europe, remains largely unknown, however, it has been estimated that about 80% of men are circumcised in the US for medical reasons [America Academy of Paediatrics, 1999], compared to about 4% in England [Rickwood A et al, 2000] and less than 2% in other parts of Europe [Frisch M et al, 1995]. There are even indications that the circumcision rate in the US is still rising [Nelson C et al, 2005].

Clinically appropriate surgery may be considered surgical treatment that is performed for a specific medical indication. The only undisputed medical indications for circumcision are pathological phimosis and recurrent balanitis [Rickwood A et al, 1999]. Pathological phimosis, by far the most common medical indication for circumcision, can be defined as the narrowing of the preputial orifice, leading to an inability to retract the foreskin, or prepuce over the glans penis [Spilsbury K et al, 2003]. It should be distinguished from physiological phimosis, which is a normal part of penile development in which preputial adhesions, located between the glans penis and the foreskin, prevent the retraction of the foreskin in young boys.

The previously reported circumcision rate of 4% in England has led some to argue that boys in England are undergoing unnecessary surgery which is not clinically indicated and therefore not clinically appropriate given that first, the incidence of phimosis has been reported to be only 0.6% [Rickwood A et al, 1989, Shankar K et al, 1999] and second, the majority of boys circumcised in England are less than 5 years of age, an age at which pathological phimosis is rare [Rickwood A et al, 2000].

Circumcision, alike any surgical procedure, carries the risk of complications. The reported complication rate following procedure varies greatly from as low as 0.06% to as high as 55% [Speert H et al, 1953, Patel H, 1966]. This variation is largely the result of the many different criteria used to define complications.

This case study utilises HES data to address the clinical question – are too many boys undergoing paediatric circumcision for phimosis of the foreskin in England?

HES data are used to report paediatric circumcision rate in England between 1997 and 2003. In addition, HES data are used to identify the determinants of outcome following the procedure.

6.2 Methods

We considered HES records related to admissions that occurred between 1 April 1997 and 31 March 2004. This time period was chosen because a unique patient identifier was introduced in April 1997, on the basis of which it is possible to link HES records that belong to the same patient.

Identification of index record and subsequent readmission

We used a three-stage selection procedure. First, we identified all HES records with an OPCS-4 code indicating circumcision (“N303”) in any of the operative procedure fields. This was labelled the index record. Second, we linked these index records with all HES records of subsequent readmissions using the unique patient identifier. Third, we deleted all HES records that related to circumcision in boys over fourteen years of age.

Identification of indications

To identify the indication for circumcision, we examined the diagnosis fields of all index records. A wide range of ICD-10 codes were identified to code the medical indications for circumcision including phimosis (“N47”, “N486”), balanitis (“N481”, “N512”), and ritual circumcision (“Z412”). Over the study period, 75,868 boys were documented to have undergone medical circumcision and 6,122 boys were documented to have undergone ritual circumcision on the basis of diagnosis coding. Boys undergoing ritual circumcision were excluded from further analysis.

Identification of complications

The codes used to identify complications were not defined in advance. Instead, we examined the diagnosis and operative fields of all hospital admissions for all boys that were likely to have had a complication of surgery – i.e. index admissions of more than one day in hospital following circumcision and 30 day readmissions after circumcision. On the basis of this examination, we were able to identify 19 diagnosis codes and 22 operative procedure codes (appendix 7) which were used to record complications following circumcision. These codes were then grouped into haemorrhagic, infectious and other complications and applied to the index and 30-day readmission records of all boys included in the study. In addition, we identified readmissions for revision circumcision (OPCS-4 code “N303” in a subsequent hospital admission after the index admission) and meatal stricture dilatation (OPCS-4 code “N79”) within a 6-month period following circumcision.

For the analysis of the complication rate, we excluded boys undergoing an additional operative procedure at the time of circumcision as the occurrence of a complication may have been influenced by the additional procedure. 9,349 (12%) boys were excluded from analysis of complications on this basis.

Statistical analysis

The HES database is structured in reporting years running from the 1st April to the 31st March. We report results from 1997/1998 to 2003/2004 (subsequently referred to as 1997 to 2003). To calculate the circumcision rate in a reporting year, we divided the number of boys who underwent circumcision in that year by the mid-year estimate of the number of boys aged between zero and 14 years living in England according to the UK Office for National Statistics [www.statistics.gov.uk].

The proportion of boys who would undergo circumcision by their 15th birthday, if the circumcision rate in a specific reporting year would remain unchanged, was approximated by multiplying the circumcision rate for boys between 0 and 14 years by 15.

We assumed that the circumcision rate estimates were Poisson-distributed counts, and Poisson regression was used to analyse trends over time. The complication rate was described as a percentage. Multivariate logistic regression was used to describe the

risk of post-operative haemorrhage according to age, indication and surgical speciality. All p values were two sided, and those less than 0.05 were judged to indicate a statistically significant result. Stata software (version 8) was used for all statistical calculations.

6.3 Results

Trends in the rate of circumcision

Between 1 April 1997 and 31 March 2004, 75,868 boys aged less than 15 years were admitted to NHS hospitals in England and underwent a medically indicated circumcision. This corresponds to a circumcision rate of 2.3 per 1000 boys per year over the whole study period.

36% (27,426) of all paediatric circumcisions were performed in boys aged less than 5, 45% (33,922) in boys aged between 5 and 9 years, and 19% (14,520) in boys aged between 10 and 14 years of age.

Over the 7-year period, the circumcision rate declined by about 20% from 2.6 per 1000 boys per year in 1997 to 2.1 in 2003. Circumcision rates were similar in the period between 2000 and 2003. The proportion of boys who would undergo circumcision by their 15th birthday if the circumcision rates observed in a reporting year would remain unchanged fell from 3.9% in 1997 to 3.1% in 2003 (Table 6.1, Figure 6.1).

The indication for the circumcision was documented in 98% of the boys included in the study. In boys with a known indication, 90% underwent circumcision for phimosis, 8% for recurrent balanitis and 2% for other reasons. Over the 7-year study period, the number of circumcisions performed for phimosis fell by 23% from 11,501 in 1997 to 8,866 in 2003 whereas the number of circumcisions performed for recurrent balanitis did not change.

The circumcision rate in boys aged less than 5 years declined over the study period by about 30% from 3.2 to 2.2 per 1000 boys per year. In boys aged between 5 and 9, the circumcision rate declined by 10% from 3.2 to 2.9 per 1000 boys per year. For boys

aged between 10 and 14, the circumcision rate increased slightly from 1.3 to 1.4 per 1000 boys per year (Table 6.1). The proportion of paediatric circumcisions performed by general surgeons, decreased by about 40% from 51% to 31% over the study period.

Complication rates following circumcision

66,519 boys who did not have an additional procedure at the time of their circumcision were included in the analysis of complications. 1.2% of these boys experienced a complication. 0.8% of boys developed haemorrhage with about 60% of these requiring a return to theatre. 1.0% (710) of boys stayed longer than one day in hospital following circumcision and 0.2% (134) were readmitted within 30 days of the procedure. 0.5% of boys required a revision circumcision and 0.01% of boys developed a meatal stricture requiring meatal dilatation within 6 months of the initial procedure (Table 6.2).

Haemorrhage was the most common complication following circumcision. We therefore investigated to what extent age, indication and surgical speciality influenced the post-operative haemorrhage rate. 0.7% of boys aged between 5 and 9 undergoing circumcision experienced haemorrhage which is about 30% lower than the rate of haemorrhage in younger and older boys (1.0%). In addition, circumcisions carried out by general surgeons had slightly lower haemorrhage rates (0.7%) compared to circumcisions performed by both paediatric (1.1%) and urological surgeons (0.8%). These observations remained with adjustment for age and indication (Table 6.3).

6.4 Discussion

Summary

According to HES data, between 1997 and 2003, the circumcision rate in England declined by 20% from 2.6 to 2.1 per 1000 boys per year. This decline was due to a drop in the frequency of circumcisions for phimosis in the period before 2000. 1.2% of boys undergoing circumcision were identified within HES as having experienced a complication following surgery, the majority of which occurred soon after surgery. Circumcision performed in boys aged between 5 and 9 had lower rates of haemorrhage than circumcision performed in younger or older boys. Moreover,

circumcisions done in boys by general surgeons had lower rates of haemorrhage than those done by paediatric or urological surgeons.

Methodological limitations

There are concerns over the accuracy of administrative data to identify boys undergoing circumcision. However, it is unlikely that coding accuracy has been a major source of error in this study as circumcision is a common procedure that is coded with a single specific OPCS-4 code. Moreover, we found there was a high degree of consistency between the coding for diagnoses and operative procedure with 98% of the admissions for circumcision containing diagnosis codes of appropriate medical indications for circumcision.

There are further concerns over the use of administrative data to capture and correctly code for complications of surgical procedures. Therefore, we specifically did not identify diagnosis and operative procedure codes relating to complications of circumcision in advance. Instead, we examined diagnosis and operative coding within HES records concerning admissions in which a complication was most likely to have occurred – i.e. index admissions in which the duration of in-hospital stay was longer than 24 hours and readmissions within 30 days. We then grouped these codes into different complication categories. By this process, we were able to account for inconsistencies in coding practice between hospitals. A further concern is that we had to rely on readmissions to capture complications becoming apparent after discharge. However, not all complications require readmission and therefore some minor complications will not have been included in our study.

Comparison with other studies reporting on circumcision rates

There is large geographic variation in circumcision rates around the world which reflects the different arguments used to justify medical circumcision. In the US, the majority of circumcisions are performed in newborn boys soon after birth [Wilkes M et al, 1990, Alanis M et al, 2004]. Arguments used to justify this practice include the prevention of urinary tract infection [T et al, 1998] in infancy as well as sexually transmitted disease in later life [Alanis M et al, 2004]. In contrast to the US, the much lower circumcision rates in Europe and Australia demonstrate that medical circumcision appears to be reserved for medical conditions affecting the foreskin.

We estimated that 3.1% of English boys would undergo circumcision by their 15th birthday, if the circumcision rate found for 2003 would remain unchanged. In the period between 1989 and 1997, this estimated proportion was found to have fallen from 6.0% to 3.8%, but the circumcision rate in boys between 10 and 14 years was found to have remained constant [Rickwood A et al, 2000]. In our study however, we found that circumcision rates began to increase in this older age group.

Comparison with other studies reporting complications of circumcision

A number of studies have reported complication rates after paediatric circumcision.[Wiswell T et al, 1989, Metcalf T et al, 1983] These complication rates vary widely which is for the greater part the result of different study types (e.g. survey, chart review, administrative data) and definitions used for complications. For that reason, we feel that we can only validly compare reported rates of return to theatre and readmission with our own results. A study of about 136,000 boys, based on administrative discharge records in the US [Wiswell T et al, 1989], found that about 0.03% went back to theatre because of haemorrhagic complications after circumcision [T et al, 1998]. The similar figure in our study is 0.5%. An explanation for this large difference is that the US study only considered neonatal circumcisions whereas the number of boys younger than 1 year of age in our study was very low (1.4%). Furthermore, we have to assume that the boys included in our study had foreskin problems to some degree, whereas in the US study most newborn boys must have had foreskins that were perfectly healthy. Lastly, the US study only considered complications during the admission in which the circumcision was performed whereas we looked at all complications that had occurred up to 30 days.

Other much smaller studies based on medical records have reported on return to theatre. A study of this type from the US observed that 3 of 240 boys (1.3%) returned to theatre with a haemorrhagic complication [Metcalf T et al, 1983], and a Canadian study observed this in 1 out of 100 boys. These figures are slightly higher than return to theatre rate for haemorrhage of 0.5% that we have found.

To the best of our knowledge, there is only one study reporting readmissions after circumcision. This prospective study, carried out in 1983 in Southampton (UK)

[Griffiths D et al, 1985], found that 4 of 140 boys (2.9%) who underwent circumcision as a day-case required an emergency readmission for haemorrhage (2 boys) and for vomiting (2 boys). Our reported readmission rate of 0.2% is considerably lower. However, the numbers in the Southampton study are small and boys were immediately discharged after circumcision, whereas in our study 1.0% of boys remained in hospital over night.

We found circumcision increasingly being performed by urological and paediatric surgeons, whereas at the same time we found that circumcisions performed by general surgeons had the lowest rate of haemorrhagic complications. These observations seem conflicting and contradictory. However, care needs to be taken when interpreting the complication rates according to surgical speciality as administrative data did not allow adjustment for disease severity.

Clinical implications

If we assume that circumcision is only performed for foreskin disease in England as opposed to the US where it is seen as a preventive health measure, HES data suggests that the circumcision rate in England remains about 5 times higher than the incidence of phimosis (0.6%) [Skankar K et al, 1999], by far the most common indication for circumcision. On the basis of these figures, it would appear that over 80% of the boys reported to have undergone circumcision in England may have been exposed to the risks of an ablative surgical procedure which is not clinically appropriate.

6.5 Tables

Table 6.1: Paediatric circumcision rates over time according to age category

Year	Age (years)									
	0-4		5-9		10-14		Total		Circumcision by 15 years (%) ²	Rate ¹
	Cases	Rate ¹	Cases	Rate ¹	Cases	Rate ¹	Cases	Rate ¹		
1997	5,024	3.2	5,415	3.2	1,966	1.3	12,405	2.6	3.9	
1998	4,921	3.1	5,861	3.5	2,146	1.3	12,928	2.7	4.1	
1999	3,896	2.5	4,826	2.9	1,939	1.2	10,661	2.2	3.3	
2000	3,596	2.4	4,409	2.7	1,935	1.2	9,940	2.1	3.1	
2001	3,467	2.3	4,413	2.8	1,973	1.2	9,853	2.1	3.1	
2002	3,335	2.3	4,521	2.9	2,194	1.3	10,050	2.1	3.1	
2003	3,187	2.2	4,477	2.9	2,367	1.4	10,031	2.1	3.1	
P value for trend	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

¹ per 1000 boys per year

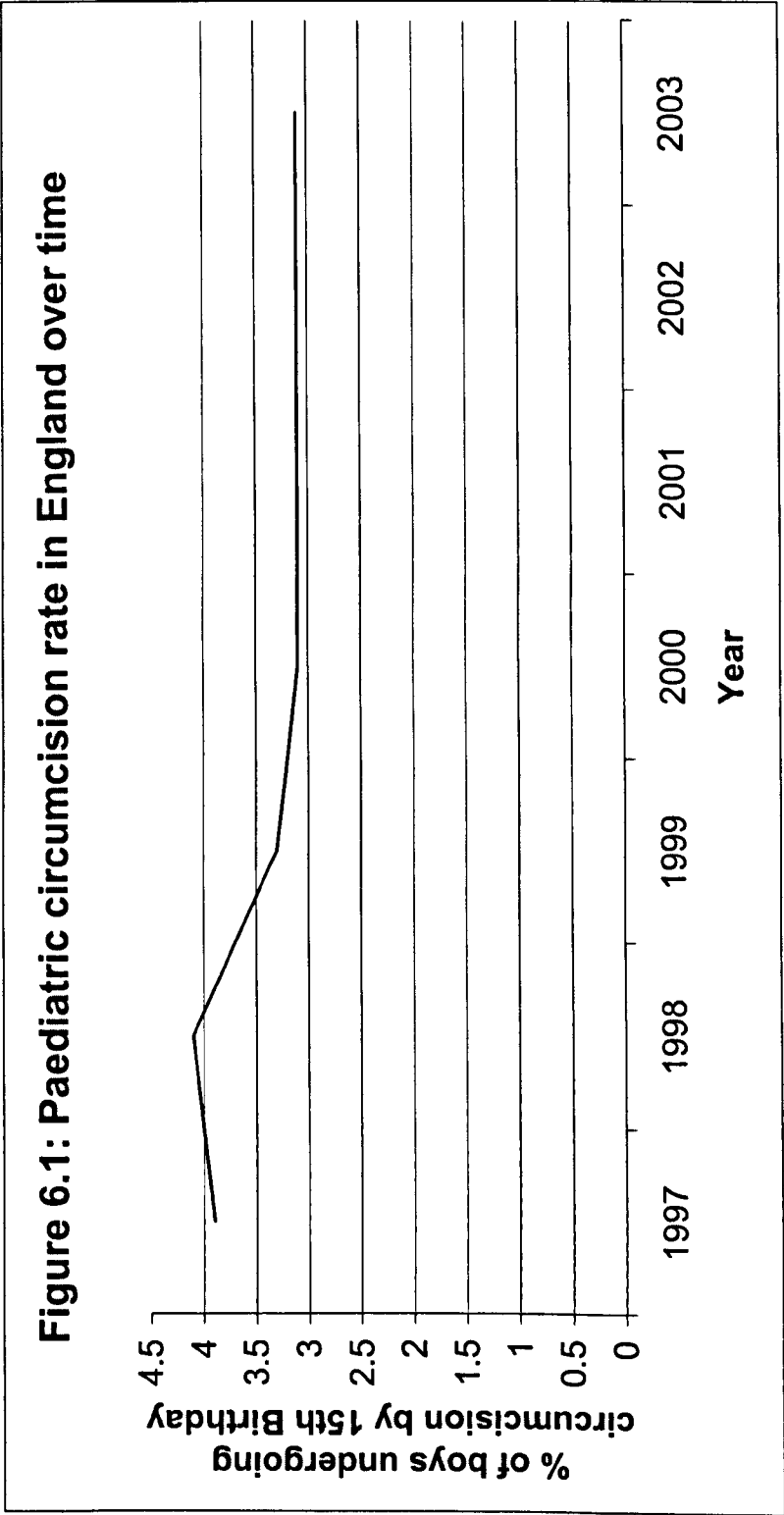
² Proportion of boys who would have undergone circumcision by their 15th birthday if the circumcision rate remained unchanged (e.g. 1997 = 0.0026 X 15 X100 = 3.9%).

Table 6.2: Short and long-term complication rates after paediatric circumcision (66,519 boys included)

	Cases	Rate (%)
Complication	789	1.2
Haemorrhage	562	0.8
<i>Haemorrhage requiring a return to theatre</i>	353	0.5
Infective/Other complications	227	0.3
Long-term complication		
6 month revision rate	303	0.5
6 month stricture rate	7	0.01

Table 6.3: Risk of post-operative haemorrhage after paediatric circumcision by age, indication and surgical speciality						
	Cases	Haemorrhage No. (%)	Unadjusted Odds Ratio (95% CI) ¹	p value ²	Adjusted Odds Ratio (95% CI) ³	p value ³
Total	66,519	562	-	-	-	
Age (years)						
0-4	22,810	223 (1.0)	1.0	0.002	1.0	0.001
5-9	30,635	218 (0.7)	0.7 (0.6-0.8)		0.7 (0.6-0.9)	
10-14	13,074	121 (0.9)	0.9 (0.7-1.2)		0.9 (0.7-1.2)	
Indication						
Phimosis	61,962	524 (0.8)	1.0	0.934	1.0	0.821
Balanitis	4,557	38 (0.8)	0.9 (0.7-1.4)		0.9 (0.7-1.3)	
Speciality						
General Surgeon	26,421	197 (0.7)	1.0	0.003	1.0	0.002
Urological Surgeon	24,691	198 (0.8)	1.1 (0.9-1.3)		1.1 (0.9-1.3)	
Paediatric Surgeon	11,136	124 (1.1)	1.5 (1.2-1.9)		1.4 (1.2-1.9)	
Unspecified	4,271	43 (1.0)	1.3 (0.9-1.9)		1.3 (0.9-1.9)	

1- odds ratio with age 0-4, phimosis and urological surgeon as baseline categories, 2 - Unadjusted odds ratio, p value for category calculated using the likelihood ratio test, 3 - Multivariate logistic regression. Adjustments were made for year of surgery, age, medical indication and speciality of surgeon.



Chapter 7

Has the incidence of primary and recurrent urinary retention changed since a shift away from surgery for the treatment of this disease?

Use of HES data to evaluate how has the change in management of Benign Prostatic Hyperplasia has influenced the incidence of acute urinary retention?

7.1 Introduction

In the early 1990's the only treatment options for men with BPH were watchful waiting or prostatectomy [Borth C et al, 2001, Barry M et al, 2001]. The morbidity and mortality associated with prostatectomy prompted searches for alternative treatments including medical therapies and minimally invasive procedures. The expansion of treatment options for men with BPH has coincided with a reduction in the use of prostatectomy, both in the US and Europe [Borth C et al, 2001, Wilson J et al, 2004, Holtgrewe H, 1998, Baine, et al, 1998] as operative intervention is increasingly being considered only as the final treatment option, both from a doctor's and a patient's perspective.

However, these alternative treatments may be less effective than prostatectomy. For example, it has previously been found that prostatectomy lowers the risk of Acute Urinary Retention (AUR – sudden inability to void urine spontaneously) in men with BPH by about a factor of 8, compared to watchful waiting [Wasson J et al, 1995], whereas the recently published Medical Therapy Of Prostatic Symptoms (MTOPS) [McConnell J et al, 2003] study found that medical treatment lowers the risk of AUR by about a factor 5. Furthermore, the comparison of the risks of AUR with surgical or medical treatment may be even more unfavourable for medical treatment than these results suggest. In the MTOPS study, AUR was part of a combined outcome also including a clinically significant increase in urinary symptoms, incontinence and urinary tract infections (“overall clinical progression”). Therefore, the reported AUR incidence is likely to be an underestimate of the true incidence as AUR was not reported if one of the other outcomes had occurred first.

Treatment of men with BPH who have experienced an episode of AUR has also changed. For example, it has been reported that the use of medical therapy (alfuzosin) can improve the short-term success rate of a trial without catheter (TWOC) in men with AUR from 48% to 62% [McNeill S et al, 2004]. However knowledge regarding the long-term outcomes after AUR still remains limited.

In this chapter, HES data is used to describe how the incidence of primary and recurrent AUR has changed in England between 1998 and 2003. In addition, HES data are used to identify changes over time both in the use of prostatectomy in men with AUR and in the frequency of AUR recurrence.

7.2 Methods

We considered HES records related to admissions that occurred between 1 April 1997 and 31 March 2004. This time period was chosen because a unique patient identifier (HESid) was introduced in April 1997, on the basis of which it is possible to link the HES records that belong to the same patient.

We used a five-stage selection procedure. First, we identified all HES records with an ICD-10 code indicating AUR ("R33") in any of the diagnostic fields. Second, we added all HES records with an OPCS-4 code indicating transurethral resection of the prostate (TURP) in any of the procedures fields ("M65"). Third, we linked all records that belonged to the same patients. Fourth, we deleted HES records related to TURP if there was no diagnostic code indicating AUR in the same record or in a linked record. Fifth, we deleted records if there was a diagnosis of prostatic cancer ("C61"), multiple sclerosis ("G35") or Parkinson's disease ("G20") in one of the diagnostic fields.

Definitions

We considered AUR to be primary if there was no HES record documenting a previous AUR in the study period. A preceding period of at least 6 months was used to determine whether a previous AUR had occurred. This duration was chosen because we observed that the time to recurrence was less than 6 months in 78% of the men who had two admissions for AUR.

Furthermore, AUR was classified as spontaneous if the primary diagnosis (i.e. the first diagnostic field in a HES record) indicated AUR or if the primary diagnosis was BPH ("N40") with a diagnosis of AUR in any of the other diagnostic fields in the same record. In addition, AUR was only classified as spontaneous if there was no

preceding admission within the last 5 days unless this preceding admission was for AUR. In all other circumstances, AUR was classified as precipitated.

Statistical analysis

The HES database is structured in yearly periods running from 1 April to 31 March, but the reporting period in this paper is shifted 6 months to create a preceding period of at least 6 months to determine whether an AUR is primary or not (see above). Results are therefore reported for yearly periods running from 1 October 1997 to 30 September 2003 (subsequently referred to as 1998 - 2003).

To calculate the incidence of AUR in a reporting year, we divided the number of men admitted with primary AUR in that reporting year by the mid-year estimate of the number of men aged 45 years and older living in England according to the Office for National Statistics. The age-specific annual incidence was calculated over the whole study period by dividing the total number of hospital admissions for primary AUR in men in specific 10-year age categories by the sum of the mid-year estimates of the number of men in those age categories.

We assumed that the incidence estimates of men with AUR were Poisson-distributed counts. Poisson regression was therefore used to test trend over time for the AUR incidence. Logistic regression was used to do the same for the proportion of AUR patients treated with surgery.

7.3 Results

Between 1 October 1997 and 30 September 2003, 165,527 men were admitted to an NHS hospital in England with primary AUR, which relates to an overall incidence of 3.06 per 1000 men per year. AUR was spontaneous in 108,139 (65.3%) of these men (Table 7.1).

Incidence of AUR fell over the study period from 3.17 in 1998 to 2.96 per 1000 men per year in 2003. This trend was more pronounced for spontaneous than for precipitated AUR (Table 7.1, Figure 7.1).

The incidence of both spontaneous and precipitated primary AUR seemed to increase exponentially with age, approximately doubling with every 10-year increase (Table 7.1, Figure 7.2).

The percentage of men with primary AUR who underwent surgery within 3 and 6 months declined between 1998 and 2003 for both spontaneous and precipitated AUR (Table 7.2, Figure 7.4). In 1998, 32% of men who had a spontaneous AUR went on to have surgery by 6 months and this figure fell to 26% in 2003. For men who had a precipitated AUR, the percentage of men undergoing surgery by 6 months fell from 7.6% to 5.8%.

The prostatectomy rate was also dependent upon the age at which men developed AUR (table 2). Men were two times more likely to have prostatectomy if they were between 55 and 84 years compared to men below and above this age range (Table 7.2).

The percentage of men with primary AUR who had a readmission for a recurrent AUR within 3 and 6 months increased between 1998 and 2003 for both spontaneous and precipitated AUR (Table 7.2, Figure 7.3). In 1998, 18% of men who had a spontaneous AUR went on to have a readmission for recurrent AUR by 6 months and this figure increased to 22% in 2003. For men who had a precipitated AUR, the percentage of men who went on to have a readmission for recurrent AUR by 6 months increased from 4.0% to 4.9%.

7.4 Discussion

HES data demonstrated a slight decline in the incidence of primary AUR between 1998 and 2003 in England. In the same period, the frequency of surgical treatment in men with primary AUR fell by about 20%, whilst the recurrence rate of AUR increased by a similar percentage. These trends were observed both in men with spontaneous AUR as well as those with precipitated AUR.

Methodological limitations

There are a number of methodological limitations associated with the use of administrative data [McKee M, 1993]. First, there are some concerns over the completeness and accuracy of the diagnostic and procedure coding process. However, a recent evaluation [www.dh.gov.uk] found that close to 100% of all patients admitted to an NHS hospital in England are included. It is unlikely that coding difficulties are a major source of error in our study of the incidence of AUR as it is an acute and severe condition that is recorded with a single specific ICD-10 code. Furthermore, if there has been a change in coding practice over the 6-year study period, it would reflect improvements in the training of clinical coders, which would have resulted in an increase in the frequency of AUR, as opposed to the decline that we observed.

Second, we considered an AUR to be a first-time event if there was no HES record documenting a preceding AUR. A limitation of this classification is that some men may have been classified as having had an episode of primary AUR when they really had a recurrence if their initial primary event hadn't been previously recorded within the HES database. This error would have influenced men in the first year of the study more than subsequent years as for subsequent years more HES database history was available to capture prior events. As a consequence, the primary AUR incidence is an overestimate in the earlier years of the study period. However, the overestimation is likely to be small, because – as explained earlier – only 22% of the recurrences occur more than 6 months after the primary event. For example, the number of admissions for primary spontaneous AUR in 1998 presented in table 2 is overestimated by less than 725 admissions ($= 22\% \times 18\% \times 18,316$). If we assume that in 1998 725 admissions were for recurrence and not for a primary AUR, we can recalculate an incidence of primary AUR of 2.01 per 1000 men per year, which is hardly different from the 2.09 that we report in table 1.

Third, the HES database contains data on hospital admissions. Our overall incidence would therefore be an underestimate as men with AUR without initial hospitalisation would not have been captured in our study. This is unlikely to have had a major effect on our results as almost all men with AUR are believed to be initially hospitalised in England. Furthermore, our time trends are unlikely to be influenced by

this limitation as there is no evidence to suggest that there has been a major shift in management of AUR over the study period.

Finally, HES data is not linked to mortality data, as a result of which we will have underestimated the AUR recurrence rates. The impact of this limitation is likely to be small as we only report on recurrence within 6 months.

AUR incidence before 1998

We studied incidence of primary AUR between October 1997 and October 2003. This study period was chosen because linkage of HES records belonging to the same patient was possible for patients admitted to hospital after April 1997, allowing a distinction between primary and recurrent AUR. However, alternative therapies for the treatment of BPH were introduced in the early 1990s. As a consequence, it is possible that the incidence of primary AUR has changed before the start of our study period.

To address this issue, we calculated the total number of admissions for AUR - without distinguishing between primary and recurrent AUR - to NHS hospitals in England in 1991, 1998 and 2003 on the basis of HES figures. We found that the number of admissions for AUR each year remained similar: 32,835 admissions in 1991, 32,223 in 1998, and 33,016 in 2003. These figures suggest that it is unlikely that the incidence of primary AUR has risen appreciably in the period before 1998. On the contrary, it is actually more likely that the incidence of primary AUR between 1991 and 1998 has fallen as we found an increase in the percentage of men with recurrent AUR between 1998 and 2003, and we have to assume that this trend had already started before 1998. If this assumption is true, a higher percentage of admissions for AUR were due to a primary occurrence of this condition in 1991 than in 1998 and 2003.

Comparison with other studies

To the best of our knowledge, this is the largest study on the incidence of primary and recurrent AUR and the first to report on time trends. A number of smaller population-based studies found incidences of primary AUR that vary around our figure of 3.06 per 1000 men per year. Two US studies reported incidences of 4.5 [Meigs J et al,

1999] and 6.8 [Jacobsen S et al, 1997] per 1000 men per year in the first half of the 1990s. A Dutch study reported an incidence of 2.2 [Verhamme K et al, 2005] per 1000 men per year in the second half of the 1990s. The higher incidence found in the US may be explained by selection bias as both US studies only included men who had responded to a detailed questionnaire. An explanation for the lower incidence found in the Netherlands may be the strict case definition used in the Dutch study requiring both evidence of a sudden inability to pass urine and catheterisation which may have been compounded by data quality problems known to exist in GP databases.

In our study, we found that around 20% of men with a primary spontaneous AUR and 4% with a primary precipitated AUR had a recurrence within 6 months. There is only limited data on recurrence after AUR, and the recurrence rates that are published are difficult to compare with the recurrence rates that we observed for a number of reasons. Most papers present only short-term outcomes after AUR and if they report on longer-term outcomes they often quote combined outcomes such as emergency surgery for AUR. Allowing for these difficulties, it can be estimated that about 50% of men with primary spontaneous AUR will have a successful trial without catheter, and that about 20% of the men that were successful will have emergency surgery for a recurrence [McNeill S et al, 2004]. This implies that about 10% of men with a primary spontaneous AUR will undergo surgery for AUR recurrence ($=50\% \times 20\%$). The overall AUR recurrence rate (recurrence treated with surgical as well as conservative treatment) in men who had a primary spontaneous AUR is therefore expected to be higher than this figure of 10%, which corresponds rather well with our observed 6-month recurrence rate of 20%.

Clinical implications

Indirect comparisons have suggested that AUR might occur less frequently in men who underwent surgical treatment than in those who had medical treatment [Wasson J et al, 1995, McConnell J et al, 2003]. This suggestion however, is not supported by the results of our study. Between 1991 and 2003, the frequency of transurethral resection of the prostate for BPH has decreased from about 40,000 to 24,000 procedures per year in England. Our study demonstrates that despite this 40% decline in the use of surgical treatment of men with BPH, the incidence of primary AUR has fallen slightly. This implies that the shift away from surgical treatment for benign

prostate disease has not resulted in an increase in the occurrence of one of the most important long-term complications of the disease. One explanation for this observed finding is that although alternative treatments for BPH, such as medical therapy, are potentially less effective at preventing AUR, more men with BPH may have been receiving some form of therapy rather than being assigned to watchful waiting. Furthermore, the increasing use of medical therapy may in effect be changing the course of the disease. This explanation is supported by a recent study from the UK [Logie J et al, 2005] which observed that the time from first treatment of LUTS to an episode of AUR increased between 1992 and 2000, most likely as a result of increasing use of medical therapy.

Another clinically relevant observation of our study is that the number of men with primary AUR who underwent immediate surgical treatment in England fell by about 20% over the six-year period, during which the recurrence rate increased by a similar percentage. Consequently, this increase in the use of conservative management for AUR seems to have put more men at risk to have an AUR recurrence. In this context, an important emerging question is therefore which men with AUR should have early surgical intervention. A number of risk factors for recurrence have been recognised [Roehrborn C et al, 2000] (e.g. old age, large prostate size, high post-void urinary residual volume, low urinary flow rate, age) and these factors might help to identify men at high risk of AUR recurrence for whom early surgical treatment may be of particular benefit.

7.5 Tables

Table 7.1: Incidence of spontaneous and precipitated primary AUR according to patient age and year in England

Age (years)	Spontaneous		Precipitated		All	
	Number of cases	Incidence	Number of cases	Incidence	Number of cases	Incidence
45-54	5,488	0.28	3,941	0.20	9,429	0.49
55-64	13,818	0.89	6,528	0.42	20,346	1.31
65-74	32,950	2.85	15,478	1.34	48,428	4.19
75-84	39,622	6.00	20,807	3.15	60,429	9.13
85-100	16,261	10.13	10,634	6.64	26,895	16.80
year ²						
1998	18,316	2.09	9,426	1.08	27,742	3.17
1999	18,641	2.11	9,741	1.10	28,382	3.21
2000	18,156	2.04	9,507	1.07	27,663	3.10
2001	18,053	2.01	9,346	1.04	27,399	3.04
2002	17,221	1.89	9,544	1.05	26,765	2.94
2003	17,752	1.91	9,824	1.06	27,576	2.96
P value for trend	<0.001	<0.001	0.13	0.001	<0.001	<0.001
Total	108,139	2.00	57,388	1.06	165,527	3.06

1 per 1000 men per year
2 a year runs from 1 October in the previous year to 30 September

Table 7.2: Surgical treatment and recurrence within 3 and 6 months after spontaneous and precipitated primary AUR

	3 months % undergoing surgery	% recurrent AUR	6 months % undergoing surgery	% recurrent AUR
Spontaneous AUR				
Age (years)				
45-54	12	15	15	17
55-64	26	15	31	18
65-74	29	16	36	20
75-84	24	17	30	21
85-100	13	15	16	19
Year				
1998	27	14	32	18
1999	27	16	32	19
2000	23	16	29	20
2001	22	16	27	20
2002	21	17	27	21
2003	20	18	26	22
p value for Trend	<0.001	<0.001	<0.001	<0.001
Precipitated AUR				
Age (years)				
45-54	1.5	2.7	1.9	3.0
55-64	5.1	2.7	6.7	3.1
65-74	6.0	3.4	8.7	4.0
75-84	5.2	4.3	7.7	5.1
85-100	2.1	4.3	3.0	5.1
Year				
1998	5.5	3.4	7.6	4.0
1999	5.5	3.4	7.6	4.0
2000	4.6	3.3	6.4	4.0
2001	3.8	3.9	5.7	4.7
2002	4.0	4.1	6.0	4.7
2003	3.8	4.1	5.8	4.9

p value for Trend	<0.001	0.001		<0.001	0.001
1 per 1000 men per year					
2 a year runs from 1 October in the previous year to 30 September					

7.6 Figures

Figure 7.1: Incidence of spontaneous and precipitated primary AUR over the study period

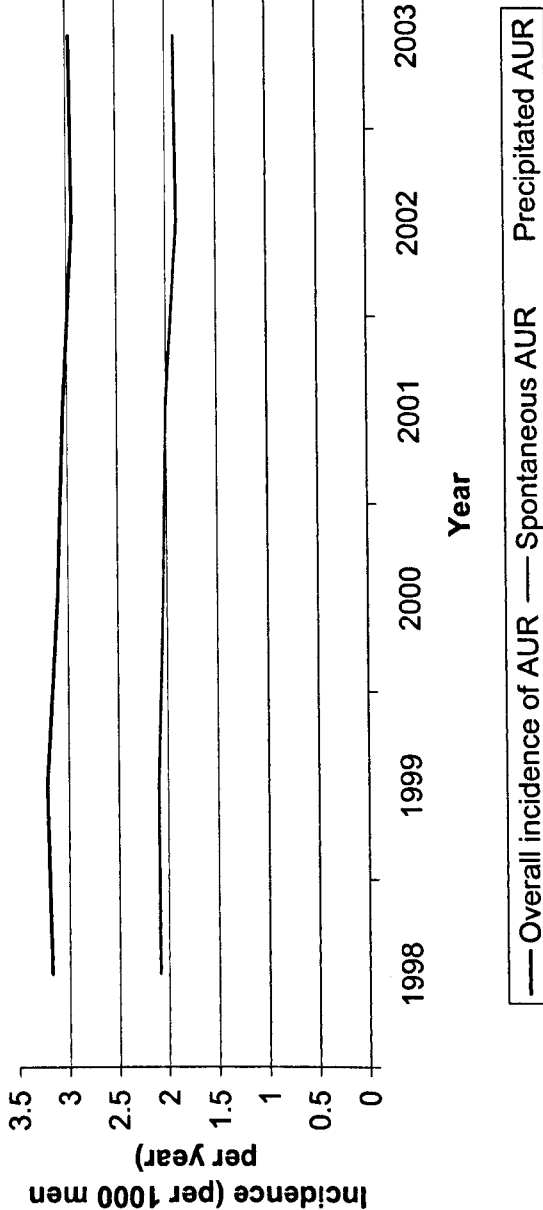
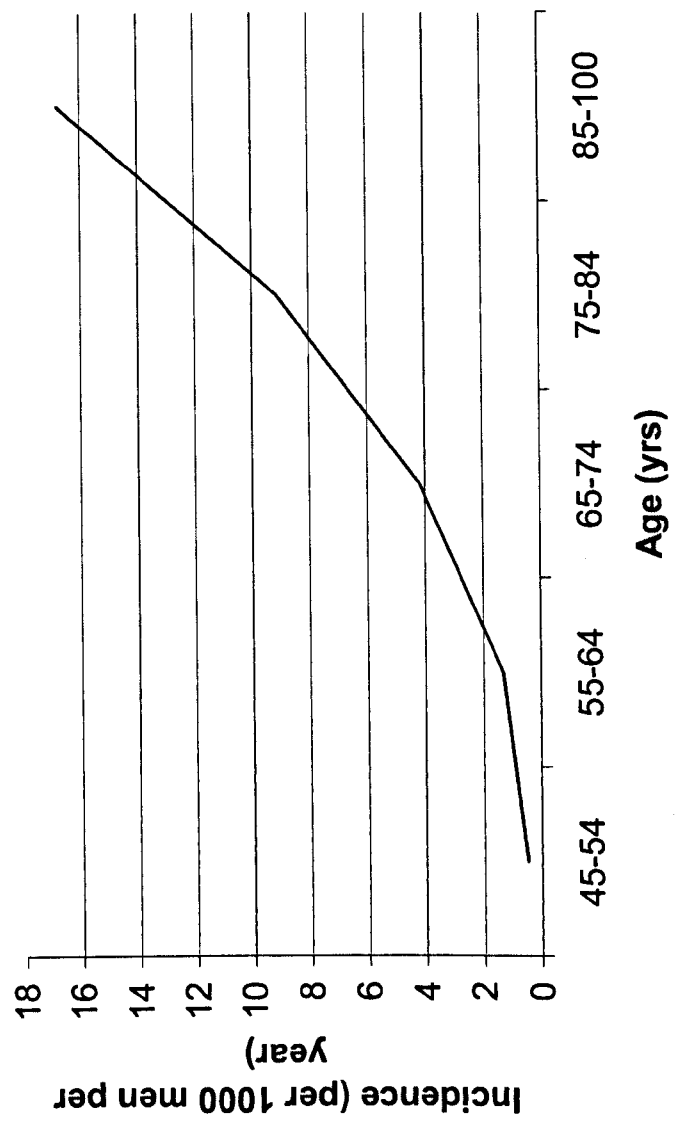
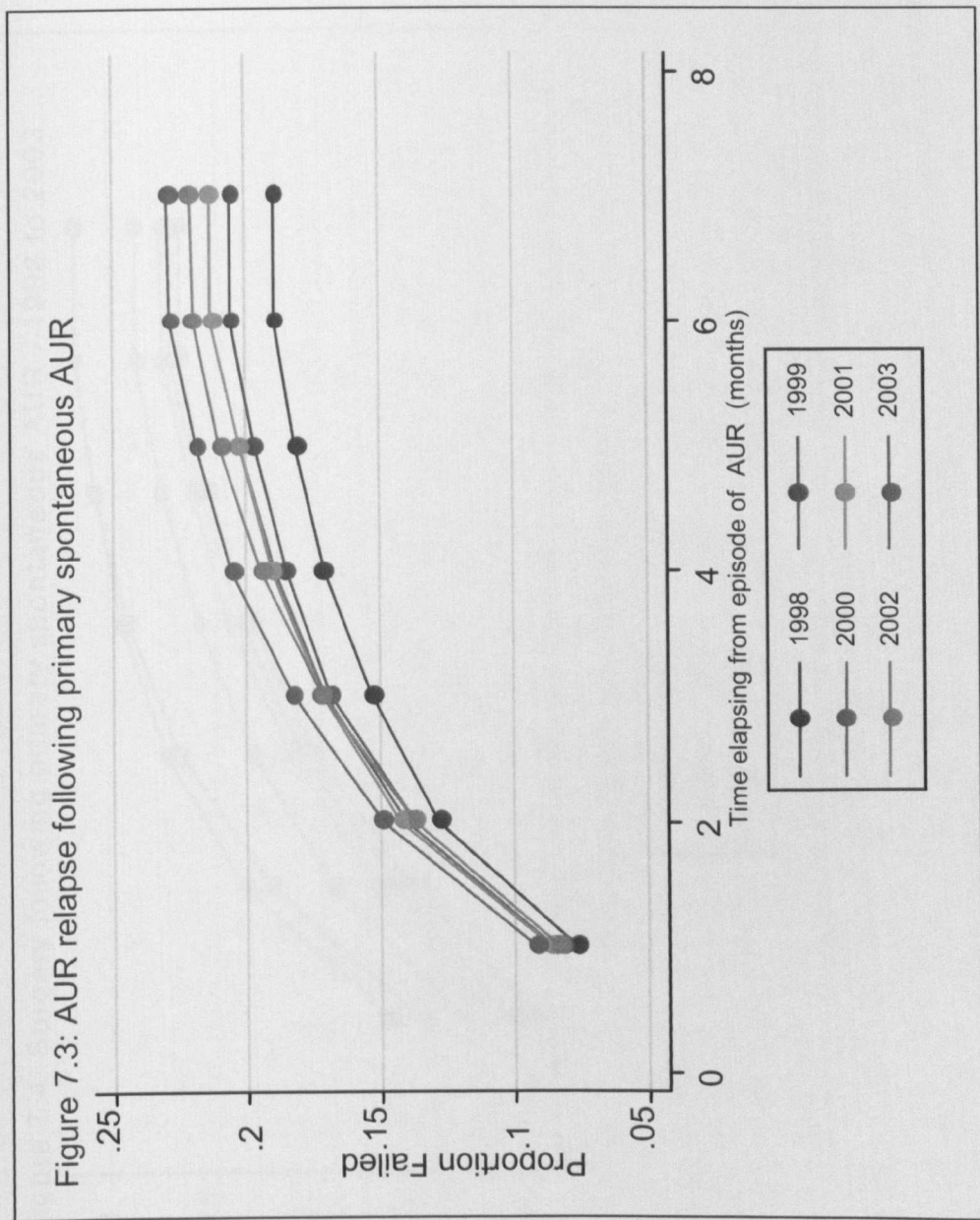
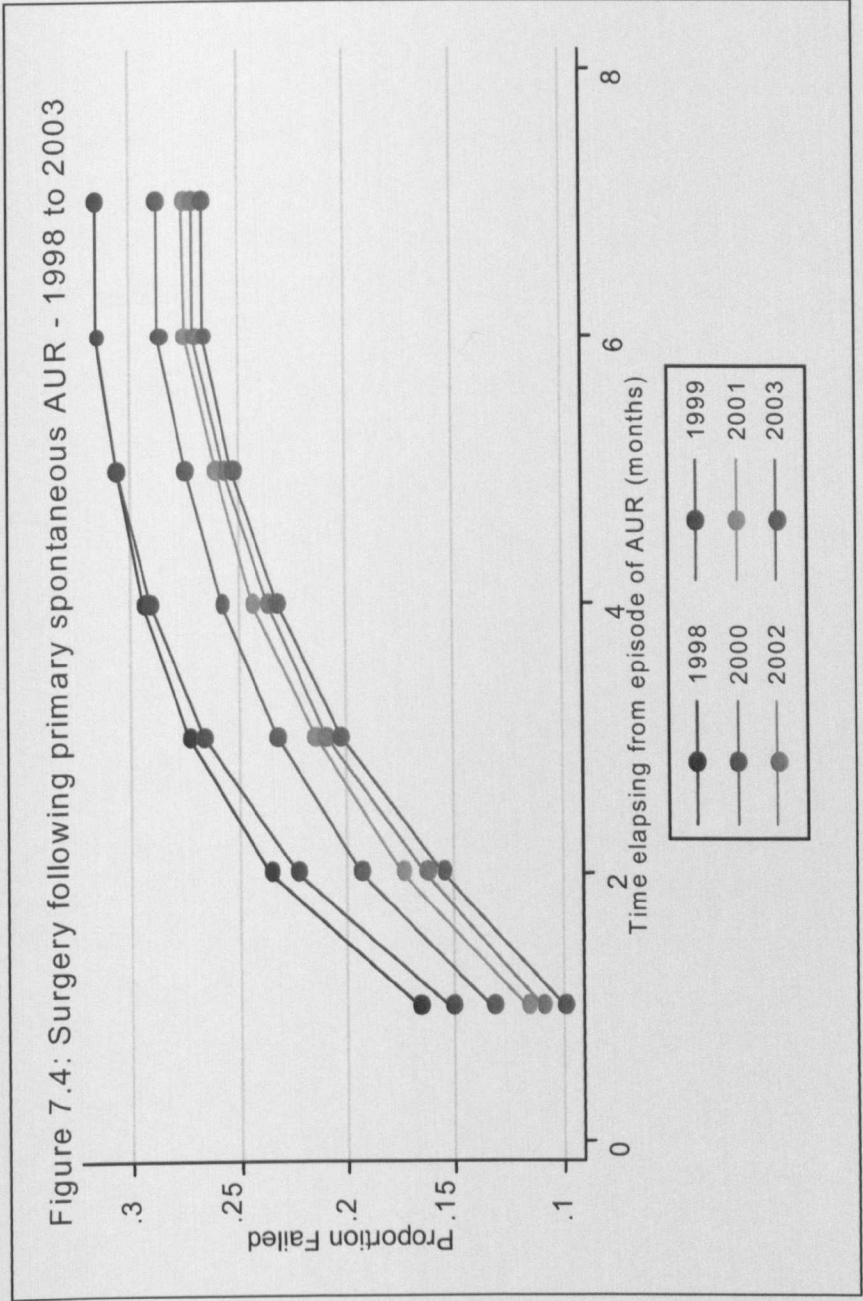


Figure 7.2: Incidence of AUR by Age







Chapter 8

Use of HES data to identify if delay in definitive cancer treatment impacts on the oncological outcome of such cancer treatment?

8.1 Introduction

Bladder cancer is the second most commonly reported malignancy of the urinary tract with an estimated 136,000 new cases diagnosed in Europe each year [Parkin D et al, 2005]. About 20% of patients newly diagnosed with bladder cancer will be found to have muscle-invasive disease [Messing E et al, 1995] for which Radical cystectomy (RC) remains the treatment of choice [Montie J et al, 1984, Pegano F et al, 1991].

A number of factors have been found to influence survival in patients undergoing RC [Skinner D et al, 1995]. These include, clinical and pathological stage, lymph node status and to some extent, the presence of concomitant co-morbid disease and patient age. There is increasing evidence to suggest that in addition to the above factors, a prolonged interval between diagnosis of muscle-invasive disease and surgery may also impact on long-term survival following the procedure.

In this case study, HES data is used to report changes over time in average preoperative delay before RC in England between 1998 and 2002. In addition, HES data is used to report the impact of preoperative delay on long-term cancer outcome. Conclusions drawn from HES data in this case study are then compared with those reported in the literature.

8.2 Methods

Patient selection procedure

We identified all HES records concerning hospital admission for RC between 1 April 1998 and 31 March 2002. This was done by examining all 7 diagnosis fields of the HES database for records containing the ICD-10 diagnosis code C67 indicating “malignant neoplasm of the bladder”. These records were then further filtered to identify records containing OPCS-4 procedure codes M341, M342, M343, M344, M348 and M349 indicating that the patient underwent RC. These records were then labelled “*index records*”.

Capturing Survival

In order to capture survival we linked each “*index record*” to national mortality records provided by the Office of National Statistics (ONS). Linkage was based on a technique of probability matching which translates the level of agreement and disagreement between each item of identifying information contained within 2 records.

Capturing Preadmissions

To capture data regarding prior hospital admission, we linked, again using probability matching, each “*index record*” to all HES records concerning hospital admission in the year before RC. This final dataset was labelled the ‘*working dataset*’.

Preoperative Delay

For each patient identified as having undergone RC within the ‘*working dataset*’, we extracted information on all diagnostic procedures related to bladder cancer, namely cystoscopy (M45) and TURBT (M42) that were performed in the year before RC. Preoperative delay was defined as the time elapsed between the most recent TURBT or the most recent cystoscopy if a TURBT had not been performed before RC, and the date of RC.

Co-morbid disease

For each patient we also extracted information on all medical conditions (coded using ICD-10 diagnosis codes) documented within HES records relating to hospital admissions in the year before RC. For each patient, we then generated Charlson co-morbidity scores [Charlson M et al, 1987] based on the extracted information using a translation of the Dartmouth-Manitoba (DM) adaptation [Romano P et al, 1993] of the Charlson co-morbidity score, as previously reported [Nuttall M et al, 2006].

Hospital Case Load

Hospital case load was defined as the annual average number of RC’s performed over the 4 year study period. Hospital case load is presented as a binary variable, contrasting hospitals performing ten or fewer RC’s per year with those performing more than ten RC’s per year. However, case load was modelled as a continuous variable when analysing the influence of case load on preoperative delay.

Exclusions

We excluded patients if we were unable to extract information concerning hospital admission for either TURBT or cystoscopy in the year preceding RC. In addition, we excluded patients recorded in the dataset as having undergone RC as an emergency procedure. Overall, our sample included 3,976 patients.

Statistical Analysis

First, we examined the association between patient/hospital characteristics and preoperative delay using linear regression. We then examined the association between preoperative delay and overall survival, calculated from the date of RC to the date of death or the date of censoring (1 April 2004, median follow-up in censored patients was 3.7 years). We used Cox proportional hazards models to assess the effect of preoperative delay on overall survival following RC, while adjusting for age, co-morbid disease, sex and hospital case load. The assumption of proportional hazards was assessed for each covariate by examining graphs of scaled Schoenfeld residuals and by appropriate statistical tests. All p values were two sided, and those less than 0.05 were judged to indicate a statistically significant result. Stata software (version 8) was used for all statistical calculations.

For our analyses, preoperative delay was initially modelled as a continuous variable. In a second model, patients were divided according to preoperative delay into 3 clinically relevant groups, less than 8 weeks (n=1,886), between 8 and 12 weeks (n=1,051) and greater than 12 weeks (n=1,039). Those patients with a preoperative delay of between 8 and 12 weeks and those with a preoperative delay of greater than 12 weeks were contrasted with those patients subjected to a preoperative delay of less than 8 weeks. We also repeated our analyses with preoperative delay represented as a binary variable, contrasting patients who waited greater than 12 weeks (84 days) with those who waited 12 weeks or less as it has previously been suggested that patients with a preoperative delay of greater than 12 weeks have a worse survival.

8.3 Results

Patient and Hospital Characteristics

The study sample included 3,976 patients undergoing RC in 192 hospitals across England between 1998 and 2002. On average, each hospital performed 11 RC's a year (range 0.25 to 38.25). Median age at surgery was 68 years (range 29 to 89), 76% (3,023) were male and 27% (1,083) had co-morbid disease (Table 8.1).

Preoperative Delay

Overall the median preoperative delay was 60 days (Table 8.1, figure 8.1). The delay was greater than 12 weeks in 26% (1,039) of the cases. However, 95% of patients underwent RC within 20 weeks of TURBT. Preoperative delay was found to be greater in men and older patients (Table 8.1 & 8.2). However, although median preoperative delay was greater in those patients with co-morbid disease, after adjusting for patient and hospital factors, this difference was no longer statistically significant ($p=0.113$).

In addition, preoperative delay, when analysed as a continuous variable, was found to be greater in hospitals with lower case loads ($p=0.021$). However, this association was no longer apparent when preoperative delay was analysed as a categorical variable (Table 8.2).

Over the four-year study period, the median preoperative delay increased from 55 days in 1998 to 65 days in 2002. Furthermore, the proportion of patients in whom surgery was delayed greater than 12 weeks increased from 20% in 1998 to 31% in 2002.

Effect of Preoperative Delay on overall survival

Overall 5-year actuarial survival was estimated at 51%. When analysed as a continuous variable, or when collapsed into our three categories (< 8 weeks, 8-12 weeks, >12 weeks), preoperative delay was not found to be associated with survival, even after adjusting for year, age, sex, hospital case load and the presence of co-morbid disease (Table 8.3, Figure 8.2). Moreover, when we repeated our analysis with preoperative delay represented as a binary variable, contrasting patients subjected to a preoperative delay of more than 12 weeks (84 days) with those having to wait 12 weeks or less, we again found no significant difference in overall survival (Table 8.3). Cox proportional hazards model assumes that the risk of death is constant over time.

To test this assumption, we estimated hazard ratios for overall survival at one year and greater than one year. We again found no significant difference in overall survival between those waiting more than 12 weeks and those waiting 12 weeks or less (Table 8.3).

8.4 Discussion

Summary

This case study has used HES data to suggest that preoperative delay before RC is increasing in England. In addition, HES data suggests that delay between diagnosis of invasive bladder cancer and subsequent radical treatment does not infer a worse outcome with regard long-term survival.

Comparison with other studies

A number of studies have reported on delay before RC, the majority of which have observed average preoperative delays similar to our figure of 60 days. Two recent European studies, one from Germany [May M et al, 204] and one from Sweden [Leidburg F et al, 2005], have reported average delays of 54 and 49 days respectively while two further studies, this time from Canada [Mahmud S et al, 2006] and the US, have reported delays of between 30 and 63 days [Chang S et al, 2003].

Preoperative delay increased over our study period by almost 20% from 55 days in 1998 to 65 days in 2002. While the majority of studies have not commentated on trends in delay, the Canadian study did note that delay in the Quebec region of Canada had increased by a factor of two from 23 days in 1990 to 50 days in 2002.

In our study, we found that increasing preoperative delay, analysed both as a continuous or a categorical variable, did not impact on survival following RC, even after adjustment for available patient and hospital factors. While there is only limited data available on this subject, the majority of which originate from retrospective case-series, the bulk of data suggest delay in radical treatment infers a worse prognosis.

Shanchez-Ortiz and colleagues reported outcome of 290 patients undergoing radical cystectomy from a single US institution. This group identified that 84% of patients

experiencing a delay of more than 12 weeks were subsequently found to have extravesical disease or positive nodal disease – both markers of more advanced disease, following surgery, compared to only 48% of patients waiting less than 12 weeks. The group went on to report 3-year survival following cystectomy identifying that survival fell from 62% in those waiting less than 12 weeks to 35% for those waiting longer than this figure. Chang and colleagues also investigated delay in cystectomy. This group's findings mirror those of Sanchez-Ortiz. In their study of 303 patients, 81% of patients waiting more than 90 days between diagnosis and cystectomy had extravesical disease compared to 52% of patients waiting for a shorter period. Mahmud and colleagues, utilising data on 1,592 patients undergoing cystectomy identified from a Canadian administrative database, found that patients waiting longer than 12 weeks had a 20% higher risk of dying than those waiting a shorter period.

It would therefore appear that conclusions gained from HES for this particular clinical question do appear at odds with the majority of data published on this topic. It certainly seems logical that the longer a patient awaits treatment for a cancer, the more likely their cancer will progress, therefore reducing the possibility of curative treatment.

Given that 95% of patients in this study underwent RC within 20 weeks of diagnosis, one explanation for why we did not find an association between preoperative delay and survival may be that patients did not experience preoperative delays of sufficient magnitude to have resulted in worse outcome. However, 20 weeks is certainly a considerably longer delay than is considered important in other studies – namely 12 weeks. Identifying how long a patient can wait before survival is compromised remains to be answered. However, our finding that preoperative delay is increasing in England does raise concern, for if this trend were to continue, patients could begin to experience preoperative delays that do compromise survival. In view of this possibility, continued efforts should be made to perform timely surgery once the decision to proceed to RC has been made.

On the other hand, inherent confounding is the most likely explanation why we did not find an association between preoperative delay and survival. HES data, like other secondary data sources, lacks detailed clinical information such as stage and grade of

disease. As a consequence, we were unable to identify and adjust for any disparities in disease severity between the different preoperative delay categories. If patients with more advanced disease and as such those with a poorer prognosis, were being prioritised to undergo surgery earlier by urologists working within NHS hospitals in England, association between preoperative delay and long-term outcome may be lost in any analyses that were unable to adjust for disease severity. Although there is no evidence that patients with more advanced disease undergo more expeditious surgery, it would certainly seem a possibility that they are. As such, the inability to account for disease severity within HES data does raise concern over the applicability and accuracy of HES data to report on whether preoperative delay influences long-term outcome of radical cystectomy. Although this is only one example where analyses of HES data to report long-term surgical outcome may be influenced by bias and confounding, it does raise concerns on the general use of HES data to comment on other determinants of long-term surgical outcome.

Methodological Limitations

Our study does have other potential limitations that must be discussed. Survival was calculated from the date of RC as opposed to the initial date of diagnosis, as we did not possess data concerning waiting list mortality. As a result, we were unable to account for either lead-time or length-time bias [Gates T et al, 2001]. Lead-time bias occurs when early surgical intervention appears to prolong survival, even when no such survival advantage exists. However, such bias is unlikely to have had a major impact on our findings', as first, we did not find that early surgery inferred a survival advantage and second, lead-time was comparatively short when compared to mean survival, even in those patients undergoing delayed RC. Length-time bias occurs when delayed surgical intervention appears to prolong survival as a result of excluding patients who die while awaiting surgery. Again, this form of bias is unlikely to have had a major influence on our findings as it is unlikely that many patients, initially thought sufficiently fit to be scheduled to undergo RC, would have died while awaiting surgery, even in those patients subjected to preoperative delays of more than 12 weeks.

Conclusion

HES data suggests that increasing preoperative delay prior to cystectomy does not impact on long-term outcome. Given that the majority of studies that have reported on this topic are at odds with this conclusion, this case study raises concerns over the ability of HES data to reliably report on the determinants of long-term oncological outcomes following surgery. The underlying reason why HES would appear inaccurate for the reporting of such outcomes is likely to stem from the inability of HES data to adjust for disease severity.

8.5 Tables

Table 8.1: Preoperative Delay by patient and Hospital characteristics

	No. Pts (%)	Median Preop Delay* (days) (IQR)	p Value	No. Preop Delay Greater Than 12 Weeks (%)**	p Value
All	3,976	60 (39-86)	-	1,039 (26)	-
Sex					
F	953 (24)	55 (37-80)		195 (20)	
M	3,023 (76)	62 (40-90)	<0.001	844 (28)	<0.001
Age group:					
Younger than 59	860 (22)	50 (33-76)		162 (19)	
60-65	792 (20)	57 (38-83)		182 (23)	
66-70	873 (22)	60 (40-89)		244 (28)	
71 or Older	1,451 (36)	66 (43-92)	<0.001	451 (31)	<0.001
Co-morbid disease:					
Absent	2,893 (73)	59 (39-84)		720 (25)	
Present	1,083 (27)	62 (41-91)	0.113	319 (29)	0.103
Hospital Case Load:					
Low	1,825 (46)	60 (39-86)		477 (26)	
High (10 or greater/yr)	2,151 (54)	59 (40-87)	0.021	562 (26)	0.592

* Linear regression, Preoperative delay analysed as a continuous variable, adjustment for age, sex, surgery calendar year, co-morbid disease and hospital case load

** Logistic regression, adjustment for age, sex, surgery calendar year, co-morbid disease and hospital case load

Table 8.2: Patient and Hospital characteristics by Preoperative Deal Category

<i>Preoperative Delay Category</i>	< 8 weeks	8-12 weeks	> 12 weeks	p Value *
Total (No./%)	1,886 (47)	1,051 (26)	1,039 (26)	-
Male (No./%)	1,375 (73)	804 (77)	844 (81)	<0.001
Median Age (IQR)	66 (59-72)	68 (62-73)	69 (63-74)	0.028
Co-morbid disease (No./%)	490 (26)	274 (26)	319 (31)	0.198
Mean Hospital Case load	11.2	11.1	10.8	0.098
* Adjusted for patient age, sex, surgery calendar year, co-morbid disease and hospital case load				

Table 8.3: Cox regression modelling survival probabilities by preoperative delay

	% 5-year survival (95% CI)	HR (95% CI)			Adjusted* First 12 Months#	Adjusted* Greater Than 12 Months*
		Crude	Adjusted*			
All Cases	51 (49-53)					
Pre-op delay	-	1.0 (1.0-1.0)	1.0 (1.0-1.0)	-	-	-
(Continuous variable)						
Preop delay (weeks)						
< 8	50 (48-53)	1.0	1.0	1.0	1.0	1.0
8-12	52 (49-56)	0.9 (0.8-1.0)	0.9 (0.8-1.0)	0.9 (0.8-1.0)	1.0 (0.9-1.2)	1.0 (0.9-1.2)
>12	51 (47-55)	0.9 (0.8-1.1)	0.9 (0.8-1.0)	0.9 (0.8-1.0)	1.1 (0.9-1.3)	1.1 (0.9-1.3)
Preop delay (weeks)						
<12	51 (49-55)	1.0	1.0	1.0	1.0	1.0
>12	51 (47-55)	1.0 (0.9-1.1)	0.9 (0.8-1.0)	0.9 (0.8-1.0)	1.1 (0.9-1.2)	1.1 (0.9-1.2)

* Adjusted for patient age, sex, surgery calendar year, co-morbid disease and hospital case load

Model restricted to follow-up year 1, patients without failure censored at end of year

* Model restricted to the end of follow-up year 1 and the end of follow-up

8.6 Figures

Figure 8.1: Distribution of preoperative delay

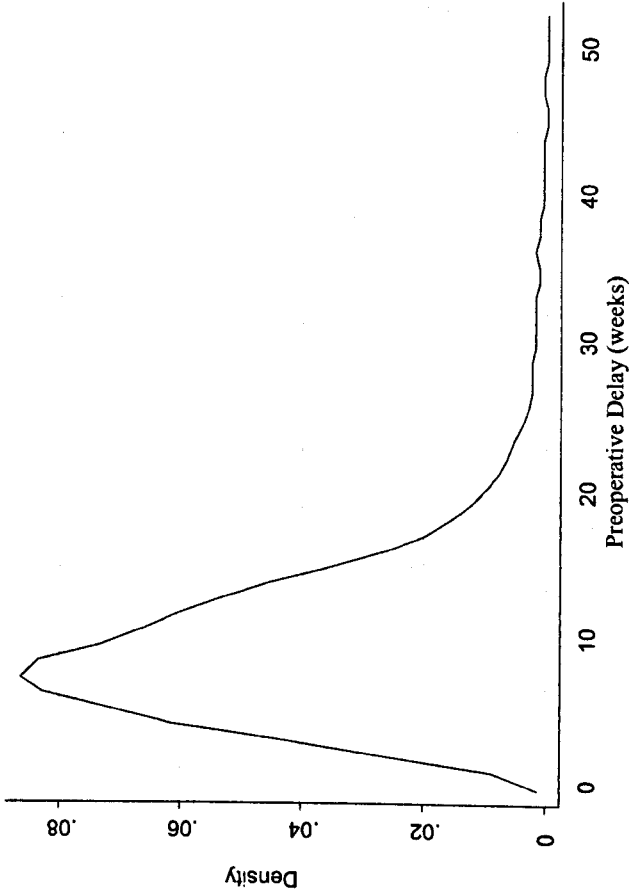
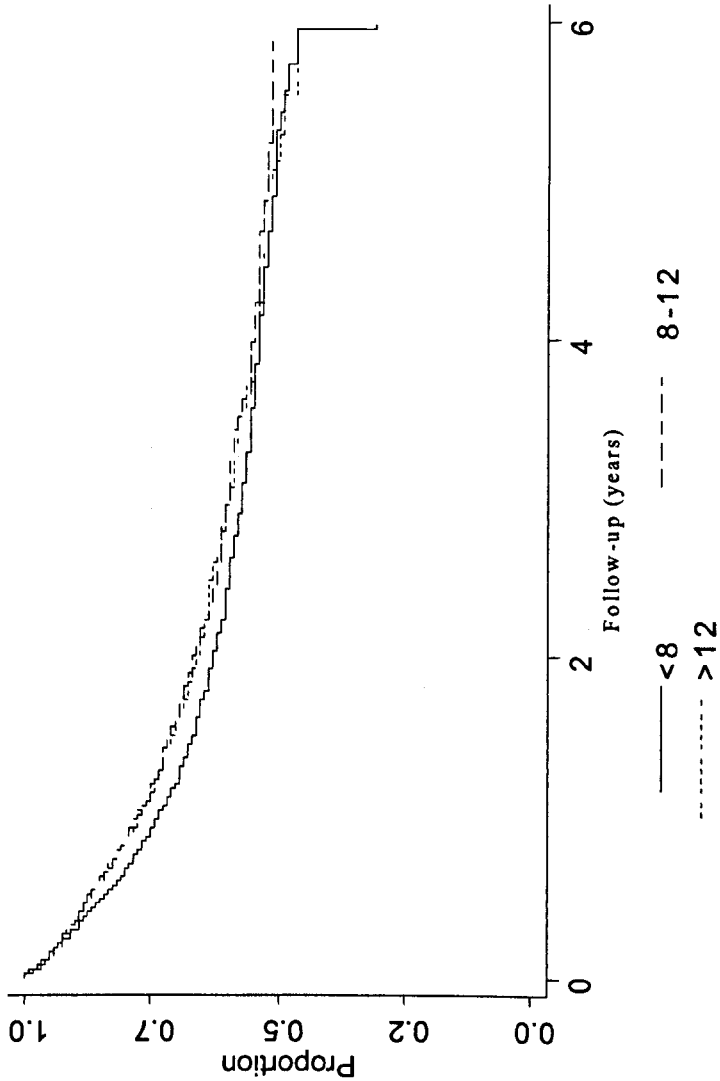


Figure 8.2: Kaplan-Meier plot of overall survival by preoperative delay



Log-rank test: $p=0.282$

Chapter 9

Use of HES data to identify how higher volume hospitals achieve improved outcomes following radical pelvic cancer surgery?

Use of HES data to investigate the determinants of short-term surgical outcome

9.1 Introduction

A number of studies have reported that high-volume centres are able to achieve improved outcomes when compared to lower-volume centres [Nuttall M et al, 2004, Finlayson E et al, 2003, Konety B et al, 2005]. This volume-outcome relationship has been demonstrated for a number of cancer surgeries including, pancreatectomy, gastrectomy, pneumonectomy, esophagogastrectomy, cystectomy [Birkmeyer J et al, Barbieri C et al, 2007] as well as non-cancerous surgeries [Gammie, 2007]. The reporting of this volume-outcome relationship for cancer surgery has led to the restructuring of cancer services both in the US and the UK [NICE Cancer Services – improving outcomes in urological cancer].

A number of hypotheses have been suggested to explain the volume-outcome relationship. However there appears little evidence to support them. A recent study from the US using the Surveillance, Epidemiology, and End Results (SEER)-Medicare dataset, reporting on 4465 patients undergoing radical cystectomy between 1992 and 1999, suggested that the volume-outcome relationship for radical cystectomy maybe explained by improved processes of care that in turn reduce the rate of adverse events after surgery [Hollenbeck B et al, 2007]. However, despite higher volume centres reporting greater rates of preoperative cardiac testing, intraoperative arterial monitoring and use of continent diversion, differences in the processes of care could only explain 23% of the volume-mortality effect. Furthermore, this finding could not be replicated in patients undergoing other cancer surgeries [Birkmeyer J et al, 2006] although has been suggested as one possible explanation why higher volume hospitals are able to achieve improved outcomes following cardiac surgery [Gammie et al, 2007].

Using data on 1864 patients undergoing gastrectomy for primary gastric cancers, a recent US study [Smith D et al, 2007] has suggested that high-volume centres may improve outcome, not by reducing the rate of adverse events following surgery, but by improving the rate of mortality after an adverse event has occurred. This has led some authors to suggest that failure-to-rescue (death after an adverse event) underlies the volume-outcome relationship and as such, represents a better measure of *quality of care* than surgical volume alone [Elting L et al, 2007].

In the present study, HES data is used to investigate to what extent failure-to-rescue explains the volume-outcome relationship in patients undergoing radical cystectomy for bladder cancer.

9.2 Methods and patient population

Patient selection procedure

We identified all HES records concerning hospital admission for RC between 1 April 1998 and 31 March 2002. This was done by examining all 7 diagnosis fields of the HES database for records containing the ICD-10 diagnosis code C67 indicating “malignant neoplasm of the bladder”. These records were then further filtered to identify records containing OPCS-4 procedure codes M341, M342, M343, M344, M348 and M349 indicating that the patient underwent RC. These records were then labelled “*index records*”. This data extraction resulted in a sample of 4,900 patients.

Patient Outcomes

Three outcomes, 30-day mortality, adverse event rate and rate of failure-to-rescue following an adverse event, were evaluated. 30-day mortality was identified by linkage of each “*index record*” to national mortality records provided by the Office of National Statistics (ONS). Linkage was based on a technique of matching each item of identifying information contained within separate data records.

To identify adverse events following surgery, we searched the diagnosis and operative fields of all records concerning patients thought likely to have had a complication after surgery – i.e. records containing data on patients who had either been in hospital for more than a week after surgery or had required readmission to hospital within 30 days of surgery. Codes used to identify adverse events were specifically not defined in advance as this was thought to limit the identification of adverse events. On the basis of our search, we were able to identify 350 diagnosis codes and 25 operative procedure codes that were used to record adverse events following radical cystectomy. These codes were then grouped according to type of adverse event, myocardial infarction, pulmonary compromise, pelvic collection, pneumonia,

operative complication, ileus/adhesions, acute renal failure, bacteraemia, wound, pulmonary embolism, stroke, cardiac arrest, respiratory arrest, gastrointestinal haemorrhage and complications associated with ileostomy (see appendix eight). These adverse event categories were then applied to the index records of all patients included in the study. Failure-to-rescue was defined as death after an adverse event.

Adjustment for case-mix

For each patient we also extracted information on all medical conditions (coded using ICD-10 diagnosis codes) documented within HES records relating to hospital admissions in the year before RC. For each patient, we then generated Charlson co-morbidity scores based on the extracted information using a translation of the Dartmouth-Manitoba (DM) adaptation of the Charlson co-morbidity score, as previously reported [Nuttall et al, 2006].

Hospital Volume

A National Cancer Guidance Steering group has been commissioned by the UK government to provide key recommendations on the organisation and delivery of cancer services [www.nice.org.uk]. This group have recently published guidance suggesting radical surgery for both bladder and prostate cancer be provided by teams typically serving populations of one million or more and carrying out a cumulative total of at least 50 such operations each year. Given these recommendations, in this study *Hospital or centre volume* was defined as the annual average number of all pelvic urological surgeries – both radical cystectomy and radical prostatectomy, performed over the 4-year study period by each individual hospital.

Hospital volume was modelled as a continuous variable when analysing the influence of volume on failure-to-rescue. However, for the purposes of presentation only, *hospital volume* collapsed into a binary variable, contrasting hospitals performing twenty-four or fewer radical pelvic surgeries per year with those performing more than this figure.

Statistical analysis

Three multivariate logistic regression models were developed. The first employed 30-day mortality (yes/no) as the response variable. A second multivariate logistic

regression model employed risk of adverse event (yes/no) as the response variable. Similar independent variables were included in the analysis. The third and final multivariate logistic regression model used failure-to-rescue (yes/no) as the response variable. Independent variables included in all three models were hospital volume – modelled as a continuous variable, age, sex, presence of comorbid disease (Charlson score of 0 versus Charlson score of 1 or more), year of surgery and admission status (elective versus emergency).

All p values were two sided, and those less than 0.05 were judged to indicate a statistically significant result. Stata software (version 8) was used for all statistical calculations.

9.3 Results

Over the four-year study, 4900 patients at 199 hospitals underwent radical cystectomy for bladder cancer. Men comprised 75.8% of the cohort, 15.3% were older than 75 years of age and 26.8% were found to have a Charlson comorbidity score of 1 or more. 26.9% (1,319/4900) experienced an adverse event while 4.0% (196/4,900) died within the 30 days of surgery. 80.1% (157/196) of which died more than 1 week after surgery.

Adjusting for patient age and sex, presence of comorbid disease, admission status and year of surgery, hospital volume was found to influence 30-day mortality (OR 0.98, 95% CI, 0.97-0.99, $p=0.02$). Hospitals performing more than 25 radical urological pelvic cancer surgeries a year had a 27% lower risk of death than those performing less than this figure.

Overall, 26.9% of patients undergoing radical cystectomy experienced an adverse event following surgery while 8.5% experienced more than one adverse event. Patient age, admission status and comorbidity status were all found to influence the risk of an adverse event occurring (Table 9.1). In multivariate analyses, patients over 75 years of age were more than 30% more likely to experience an adverse event (OR 1.37, 95% CI, 1.17-1.60, $p<0.001$) than those patients younger than 75, while patients identified with a Charlson comorbidity score of 1 or more were nearly twice as likely

to experience an adverse event than those without comorbid disease (OR 1.90, 95% CI 1.66-2.18, $p<0.001$). Patients undergoing elective, as opposed to emergency surgery were also at lower risk of an adverse event (OR 0.72, 95% CI 0.56-0.93, $p=0.01$) (Table 9.1).

However, hospital volume was not found to independently predict the risk of an adverse event occurring following surgery (OR 1.00, 95%CI, 0.99-1.00, $p=0.13$) (Table 9.1).

Overall, failure-to-rescue following an adverse event occurred in 10.2% (134/1,319) of patients. Patient age, comorbidity status, year of surgery and hospital volume were all found to influence failure-to-rescue rates following an adverse event (Table 9.2). In multivariate analyses, patients over 75 years of age were more than 80% more likely to die following an adverse event (OR 1.83, 95% CI, 1.25-2.71, $p=0.002$) than those patients younger than 75, while patients with a Charlson comorbidity score of 1 or more were nearly twice as likely to die following an adverse event than those without comorbid disease (OR 1.99, 95% CI, 1.37-2.89, $p<0.001$). Failure-to-rescue rates were found to have fallen from 12.9% in the first year of our study to 6.6% in the last year of our study (OR=0.84, 95% CI, 0.71-0.99, $p=0.03$).

Hospital volume also influenced the rate of failure-to-rescue following an adverse event (OR 0.98, 95% CI, 0.97-0.99, $p=0.026$) (Table 9.2). Hospitals performing more than 25 radical urological pelvic cancer surgeries a year had a 37% lower risk of failure-to-rescue following an adverse event than those performing less than this figure. Moreover, the impact of hospital volume on the rate of failure-to-rescue appeared to be influenced by the number of adverse events the patient experienced. Patients experiencing more than 1 adverse event in a hospital performing more than 25 radical urological pelvic cancer surgeries a year had a 66% lower risk of failure-to-rescue than those performing less than this figure, (OR 0.44, 95% CI, 0.23-0.85, $p=0.01$).

The most common adverse events following radical cystectomy were operative complications of surgery, for example post-operative haemorrhage or dehiscence of wound (7.4%), post-operative ileus/ adhesions (6.3%), pelvic collection/bowel leak

(6.3%) and myocardial infarction (4.0%) (Table 9.3). The highest failure-to-rescue rate was seen for myocardial infarction (21.1%), followed by pulmonary compromise (20.4%) and acute renal failure (18.7%). Treatment at a higher volume centres seemed to decrease the odds of failure-to-rescue following myocardial infarction, pulmonary compromise and pelvic collection/bowel leakage, although these trends did not reach statistical significance (Table 9.3).

9.4 Discussion

Summary

As previously reported, this study found that increasing hospital volume is associated with improved 30 day survival following radical cystectomy. However, our study also demonstrates that higher volume hospitals are able to achieve improved outcomes by reducing the rate of failure-to-rescue following an adverse event.

Comparison with other studies

In our study, we found that patients undergoing radical cystectomy in centres performing more than 25 pelvic cancer surgeries a year were 27% less likely to die in the perioperative period than those treated at centres performing less than this figure. This finding is similar to that reported in a recent US study that utilized data from both the national Medicare claims database and the Nationwide Inpatient Sample. In this study, in-hospital mortality rates was 6.4% for very low volume centres (< 2 radical cystectomies a year) compared to only 2.9% for very high volume centres (> 11 radical cystectomies a year) [Birkmeyer J et al, 2002]. Moreover, our findings are in keeping with several systematic reviews recently published on this subject (Nuttall M et al 2004, Konety B et al, 2005).

We report an overall adverse event rate of 26.9%. This is not dissimilar to other studies. A recent paper [Quek M et al, 2006], reporting on 1,359 patients undergoing RC at a single US institution between 1971 and 2001, found that 32% experienced an adverse event, the most frequent of which was sepsis. In comparison, two recent population-based studies, using data from the National Inpatient Sample (Konety B et al, 2006) and the National Surgical Quality Improvement Programme (Hollenbeck B

et al, 2007), have reported post-operative adverse event rates, identified using a similar methodology to that employed in this study, of 28.4% and 30.5% respectively.

We found that while hospital volume did not influence the rate of adverse events, it did however appear to impact on the rate of failure-to-rescue following an adverse event. This is similar to that reported for patients undergoing radical gastrectomy. [Smith D et al, 2007], using data from the Texas Hospital Public Data File, which found that for patients undergoing surgery at high and low volume centres, the rate of failure-to-rescue following radical gastrectomy improved from 7.1% for centres performing between 3 and 15 gastrectomies a year, to 1.9% for those centres performing more than 15 gastrectomies a year. In our study, the rate failure-to-rescue fell from 11.5% for centres performing fewer than 25 pelvic surgeries a year to 7.6% for centres performing more than this figure. Using the same data source, Elting et al, have investigated the impact of hospital volume on the outcome of radical cystectomy. In this study, rates of in-hospital mortality were also found to be significantly lower for high volume centres (>10 radical cystectomies a year). In addition, hospital volume also appeared to influence the rate of failure-to-rescue following an adverse event, although this trend did not remain statistically significant in multivariate analyses. Further analysis of their data suggested that, not only were the majority of deaths after radical cystectomy a result of failure-to-rescue, but also that a high nurse-to-bed ratio resulted in a 60% reduction in the rate of failure-to-rescue.

Several other studies, in addition to this study, have sought to identify the mechanisms underlying the volume-outcome relation. Hollenbeck and colleagues, reporting on 4465 patients identified, using the Surveillance, Epidemiology, and End Results (SEER) data-set, as having undergone radical cystectomy between 1992 and 1999, found that high and low volume centres differ with regard to many processes of care, before, during and after surgery. However, the actual differences in the use of processes of care, such as arterial monitoring, were only found to explain 23% of the volume-mortality effect. Furthermore, when the same group evaluated this hypothesis on patients undergoing other cancer surgeries such as lung and gastric resections, differences in measurable processes of care could not explain the volume-outcome effect on mortality.

In our study, we found higher volume centres tended to have lower rates of failure-to-rescue following adverse events such as myocardial infarction, pulmonary compromise and bowel leakage. While there is little published data available on the influence of hospital volume on the management of adverse events occurring after surgery, Chen and colleagues [Chen J et al, 1999] have identified, certainly for myocardial infarction, that patients are more likely to receive more effective medical management of in high volume centres compared to those patients in lower volume centres.

Clinical Implications

This study suggests first, that unlike high-risk cancer surgery e.g. oesophagectomy [Birkmeyer et al, 2002], the majority of deaths after radical pelvic surgery do not occur intra-operatively, rather from failure-to-rescue after adverse events (>80%) and second, that lower volume centres may be able to replicate outcomes of higher volume centres by improving their rates of failure-to-rescue after an adverse event occurs.

How centres may achieve improve their rates of failure-to-rescue however, does require further research. It is likely that improved access to interventional cardiology services as well as increased availability of assisted ventilation within the intensive care setting plays a role and as such improved availability of these services in lower volume centres could lead to improved outcome in these centres.

However, financial constraints as well as limited availability of clinical expertise may mean that these services are themselves centralised and as such, lower volume centres may not have access to them. In this way, it may be the centralisation of cardiac and intensive care facilities that limits the capability of low volume centres to provide a radical pelvic surgery service. On the other hand, if it is the per-operative management that is important in managing patients undergoing radical pelvic surgery, it may be that surgeons from lower volume “home” centres could travel, together with their patients, to more centralised high volume centres to perform the surgery.

Although the main drivers of patient outcome after radical pelvic surgery are patient factors such as age and comorbidity, this study does support recommendations, both in the US and Europe, that radical pelvic surgery continues to be performed in large high volume centres. However, this study suggests that volume itself should not be necessarily be used as a proxy for quality as availability of cardiac and intensive care facilities would appear the most influential factors in patient outcome.

Methodological limitations

These findings should be interpreted with a few caveats. First, outcome of adverse events following surgery may appear worse if hospitals only identify very severe complications. In such a way, if clinical coders in low volume centres failed to recognise more subtle, less severe, adverse events where outcome is likely to be better, low volume centres would artificially appear to have worse rates of failure-to-rescue. To investigate this we compared the recording of complications in patients dying within 30 days of surgery, a cohort of patients expected to have a recorded adverse event, given they died so soon after surgery. We found a documented adverse event in 68.3% of patients dying within the first 30 days of surgery having had surgery in a low volume hospital compared to 67% in our high volume hospital category, a difference that was not found to be statistically significant (Table 9.4). This suggests that better outcome of complications identified in higher volume is unlikely to result in lower volume hospitals only coding more severe adverse events.

Although the majority of studies exploring the volume-outcome relation use administrative data such as HES data, administrative by its nature is limited in its ability to adjust for case-mix. While we have attempted to adjust for the presence of co-morbid disease using an adaptation of the Charlson co-morbidity scores, administrative data does not contain data on cancer specific parameters and as a result we were unable to adjust for cancer severity. While it would be optimal to adjust for these parameters, lack of adjustment is unlikely to have had a major effect on our findings, as severity of bladder cancer is more likely to influence long-term survival rather than 30-day mortality.

Further research

More research is urgently required to understand and investigate why failure-to-rescue rates vary between the different centres performing radical pelvic surgery, both to enable lower volume centres to improve by learning and adopting best practices, as well as enable higher volume centres to improve outcomes still further.

Conclusions

HES data suggest higher volume centres are able to achieve improved outcomes of radical pelvic surgery by reducing the rate of failure-to-rescue following an adverse event, most notably for myocardial infarction and pulmonary compromise.

Improvement in outcome of radical pelvic surgery is likely to be achieved by improving access at an early stage to specialists in cardiac and intensive care medicine.

9.5 Tables

Table 9.1: Risk of adverse event after radical cystectomy		
Multivariate		
	P value	Odds Ratio (95% CI)
Hospital volume	0.13	1.00 (0.99-1.00)
Age	<0.001	1.01 (1.01-1.02)
Year	0.69	0.98 (0.93-1.04)
Elective	0.01	0.71 (0.55-0.92)
Comorbid disease	<0.001	1.89 (1.65-2.18)
Sex	0.87	0.98 (0.84-1.14)

Table 9.2: multivariate analysis of failure-to-rescue following an adverse event					
	1 of more adverse events		2 or more adverse events		
	P value	Odds Ratio (95% CI)	P value	Odds Ratio (95% CI)	
Hospital volume	0.02	0.98 (0.97-0.99)	0.001	0.96 (0.94-0.98)	
Age	<0.001	-	0.001	-	
Year	0.01	-	0.49	-	
Elective	0.66	-	0.41	-	
Comorbid disease	<0.001	-	<0.001	-	
Sex	0.84	-	0.85	-	

Table 9.3. Multivariate analyses evaluating rates of failure-to-rescue for individual adverse events by hospital volume

Adverse event	Incidence (%)	Failure-to-rescue (%)	P value	OR (95% CI)
All Events	26.9	10.2	0.02	0.98 (0.97-0.99)
Myocardial Infarction	4.0	21.1	0.06	0.97 (0.95-1.00)
Pulmonary Compromise	2.2	20.4	0.05	0.96 (0.93-1.00)
Pelvic collection	6.3	4.5	0.05	0.96 (0.92-1.00)
Pneumonia	2.9	17.5	0.75	1.00 (0.98-1.03)
Operative Complication	7.4	8.0	0.10	0.96 (0.94-1.01)
Ileus/adhesions	6.3	7.7	0.25	0.98 (0.95-1.01)
Acute Renal failure	2.8	18.7	0.83	0.99 (0.96-1.02)
Bacteraemia	1.7	16.7	0.49	0.98 (0.93-1.03)

Table 9.4: Coding of adverse events following surgery by hospital volume		
Hospital volume	0-24 pelvic surgeries each year	>24 pelvic surgeries each year
% (No.)		
30-day mortality	4.4 (141/3,214)	3.3 (55/1,686)
Deaths with a coded adverse event	68.8 (97/141)	67.3 (37/55)

Section Four

General Discussion

Chapter 10**General Discussion**

10.1 Objectives

This section is divided into four subsections, the first of which represents a brief summary of the thesis.

In the second subsection, the strengths and weaknesses of the HES database are discussed in the context of the case studies included within this thesis. Such strengths and weaknesses are subsequently compared with those gained from studies that have investigated the use of databases other than HES.

In subsection three, recommendations are made concerning the use of the HES database to answer clinical questions concerning incidence of urological disease as well as practice and outcome of urological surgery based on the strengths and weaknesses of the database identified in this thesis. Finally, the type of clinical questions that can and can't be answered using the HES database as a source of data are speculated upon based on the strengths and weaknesses of the HES database identified within this thesis.

The fourth and final subsection of this general discussion concerns suggestions for future work, including the need for further validation studies to assess the accuracy of HES data as well as the need for collaborative work to link the HES database with additional national databases.

10.2 Summary of thesis

Section one

Section one was an introduction to, and overview of, this thesis. It set out the objectives of the thesis and named the urological diseases utilised within this thesis to evaluate the HES database as a source of data to answer clinically important questions.

Background information was presented on the growing emphasis of clinical governance, the increasing demand for measures of clinical quality and outcomes reporting together with the need for increasing data concerning disease occurrence

and surgical practice within the NHS. The five individual case studies within this thesis were subsequently introduced and expanded upon together with an explanation as to why they were chosen to evaluate the HES database as a source of information.

Chapter two went on to briefly summarise the urological diseases and urological surgeries on which the case studies included within this thesis are based.

Section Two

Chapter three introduced the HES database and how HES data is collected together with how HES data records may be linked to Office of National Statistics (ONS) mortality records. In addition, this chapter set out how the HES data utilised within this thesis was obtained from the Department of Health in England.

Chapter four presented a review of the published literature to identify to what extent the HES database has previously been used to answer specific clinical questions regarding, first, the incidence of urological disease and second, the processes and outcomes of urological surgery. The review highlighted the completeness of the database identifying very low under-ascertainment when compared to local audit data but on the other hand identified that use of Finished Consultant Episodes (FCE'S) over-estimated disease incidence by up to 56%. The review identified that use of a combination of date of birth, postcode, discharge destination, and episode order could dramatically reduce such over-estimation of disease incidence. In addition, the review identified that although the majority of studies that have reported outcomes of surgery using HES data have restricted their analyses to reporting of the determinants of in-hospital mortality, several authors have drilled down into HES data to identify other indices of quality available within HES. These included, the percentage of FCE's with a coded complication - identified by searches of HES records to identify diagnostic and operative coding adverse events, the percentage of FCE's with a prolonged length of stay, mean length of spell and the percentage of FCE's in which patients undergo more than one operative procedure.

Section Three

This section included the five case studies on which recommendations concerning *“the use of the HES database to answer clinical questions”*, included within this general discussion are based.

Chapter five presented a study developed to evaluate the feasibility of using HES data to report trends over time in the incidence of hypospadias using frequency of corrective hypospadias surgery captured within HES as a proxy for the incidence of the congenital anomaly. Data from this case study was then compared with that generated from a registry of congenital anomalies – a data source known to have high under-ascertainment. The study demonstrated that incidence estimates of corrective hypospadias surgery were more than three times higher than that reported by the National Congenital Anomaly System (NCAS), with the difference in incidence estimates being compatible with the previously reported under-ascertainment to NCAS. Furthermore, the study suggested the incidence of this important congenital anomaly is increasing in England. This case study therefore provided evidence that incidence estimates, based on treatment obtained from the HES database, may represent a more comprehensive source of data than pre-existing congenital anomaly registries.

Chapter six presented a study developed to evaluate the use of HES data to identify the clinical appropriateness of treatment with regard use of paediatric circumcision for the treatment of pathological phimosis – a condition with a well documented incidence. The study identified that the incidence of circumcision in England remained 5 times higher than the incidence of phimosis, and as such the study concluded that over 80% of the boys undergoing the procedure were being exposed to the risks of an ablative surgical procedure which was not clinically appropriate. This case study therefore provided evidence that where the incidence of a surgically treatable disease is reliably known, HES data can be used to identify unnecessary or clinically inappropriate treatment.

Chapter seven presented a study designed to evaluate the use of HES data to report the impact of change in management on urological disease. The example used was Benign Prostatic Hyperplasia (BPH) as the management of BPH has changed

dramatically over the last decade with far fewer men undergoing surgery. The outcome measure used to evaluate the impact of change in disease management was acute urinary retention as this is a known complication of BPH disease progression and therefore potentially influenced by a change in the way men with BPH were managed. The case study suggested that despite a shift away from surgery, there was no change in the incidence of acute urinary retention over the last decade suggesting men were not being placed at increased risk of BPH disease progression as a result of fewer surgical procedures being performed for the disease. On the other hand, the study did suggest that the adoption of Trial Without Catheter (TWOC) policies in men who had experienced an episode of urinary retention, advocated by randomised controlled trials that have demonstrated reasonable success rates after TWOC's for men with acute urinary retention, have resulted in real-life increases in recurrent retention of urine. This case study therefore provided evidence that HES data may be used to monitor the impact of changes in management and treatment of disease.

Chapter eight presented a case study designed to evaluate the use of HES data to assess the impact of time from bladder cancer diagnosis to treatment. The case study found that patients were waiting longer between diagnosis and subsequent treatment, but on the other hand suggested that delay in treatment did not appear to influence long-term oncological outcome. This finding was at odds with the majority of published data that have investigated this particular clinical question. This case study therefore provided evidence that HES data may not be suitable for the reporting of determinants of long-term outcomes following surgery.

Chapter nine presented a case study designed to evaluate the use of HES data to investigate the determinants of peri-operative outcome following radical pelvic cancer surgery. The study was specifically designed to use the HES database to ask how high volume cancer centres achieve better short-term outcomes following radical cystectomy for bladder cancer. This case study demonstrated that high volume cancer centres have similar complication rates following surgery, but that patients experiencing a complication of surgery were less likely to die following that complication than a patient experiencing a similar complication in a lower volume cancer centre. This case study therefore provided evidence that HES data may be used

to investigate the determinants of short-term surgical outcome, if not longer-term outcomes as suggested in the previous case study.

10.3 Strengths and weaknesses of using HES data to answer clinically relevant questions

The review along with each case study illustrated different strengths and weaknesses of the HES database when used by the urologist to answer clinical questions. These must be discussed as they form the basis on which recommendations for the use of the database may be made.

The literature review that investigated the use of HES to study incidence, surgical treatments and their outcomes identified a key strength along with several weaknesses of the database. The review highlighted the completeness of the HES database demonstrating that HES data, when compared to large local audit data had *minimal under-ascertainment*. On the other hand however, the review identified that use of Finished Consultant Episodes (FCE'S) to report incidence of surgical conditions can lead to dramatic over-estimation of disease incidence in the order of 1 and 56%. However, the review did identify that this figure could be greatly reduced using methods to identify patient level figures as opposed to simply using FCE's. These methods included use of only first order episodes within admission spells (i.e. those HES records labelled EPIORDER 1), use of date of birth, postcode, discharge destination, date of episode start, all of which attempt to reduce the double-counting of episodes.

The review also demonstrated that HES data had few outcome measures available to evaluate the processes and outcomes of surgery – namely in-hospital mortality. This certainly represents a weakness of the database to evaluate the outcome of surgery as for many procedures, death, is an extremely rare outcome event and so is not particularly helpful for the evaluation of '*quality of care*'. However the review did identify that it is possible to identify alternative outcomes measures. These included amongst others, searching for specific codes known to be associated with an adverse event, identifying those with prolonged lengths of stay and reporting the percentage of spells with more than one operation.

Another weakness identified from the review of HES is that it is difficult within HES to adjust for confounding variables when analysing the determinants of outcome of surgery. On the other hand the review did identify that some have developed methods by which confounding can at least in part be accounted for. These include, identifying those admitted as an emergency as opposed to undergoing elective admission and those with co-existing comorbid disease e.g. identification of those patients with Downs syndrome undergoing paediatric cardiac surgery.

The first case study utilised the HES database to report on the incidence of corrective hypospadias surgery. This case study highlighted the first major strength of the database, namely its comprehensive nature. It was due to this comprehensive nature that incidence estimates generated from HES for hypospadias were more than three times higher than the incidence of hypospadias reported over a similar period by the national surveillance registry - NCAS. Furthermore, this difference appeared compatible with the estimated under-ascertainment to NCAS further demonstrating the strength of the HES database to capture disease within society.

On the other hand, despite the incidence estimate for hypospadias being three times higher than the figure quoted by NCAS, the use of operative codes – as was the case in this study, as a surrogate for disease itself may represent a weakness of the HES database as estimates based on surgical activity may under-estimate incidence of disease as it presumes all patients with the disease will undergo surgery. Certainly this was one weakness of the hypospadias case study, for boys with very minor forms of the congenital disorder may not have undergone surgery, the effect of which would have been an under-reporting of the true incidence of the condition. Furthermore, if there had been a trend towards boys undergoing surgery for more minor cases over time, this could have suggested a rising incidence where this was not the case. This of course could be true of numerous conditions if surgery for that condition were to be used as a surrogate marker for the condition itself.

Another weakness identified by the hypospadias case study, although not applicable to the hypospadias itself, was the finding that medical conditions can be treated by more than one surgical procedure. The effect of this within the HES database is that

potentially several operative codes may be required to be grouped together to provide a single variable which could subsequently be used to calculate the incidence for that particular medical condition. While this was not the case for hypospadias – corrective surgery for hypospadias has only one single code – “*hypospadias repair*” (M731), this would be the case for many other conditions. Furthermore, as highlighted in our case study that evaluated the use of the HES database to identify complications following radical cystectomy, the only method to correctly identify the specific codes utilised by clinical coders is to review the data itself.

The final weakness of the HES database identified by the hypospadias case study concerns the identification of the index episode. If a patient could undergo more than one procedure to treat a surgical condition, it is essential to identify index admissions to prevent double counting which will in turn result in inflated incidence estimates. Identifying index admissions is achieved by labelling HES data records with use of HESid numbers and then trawling the database to identify other records concerning the same patient undergoing a similar procedure e.g. “*hypospadias repair*”. However, one weakness of the HES database is that to identify an index admission, sufficient database history must be available to search for earlier admissions. Clearly patients undergoing surgery in latter database years will have greater database histories in which to search for earlier procedures, the result of which is an artificial decrease in the incidence of the condition over time.

The second case study utilised the HES database to report on the incidence of circumcision. This case study again demonstrated the comprehensive nature of the HES database to reflect national practice which in turn could be compared to data concerning the incidence of a condition. In addition, this case study also clearly demonstrated the great advantage of HES in that data was available over a significant time period which in turn could provide information on the changing trends in the incidence of disease.

However, the case study did raise questions concerning the accuracy of diagnostic coding within the database. More than 90% of boys undergoing circumcision were coded as undergoing the procedure for phimosis, more than five times the known incidence of the condition. While this may reflect unnecessary surgery, it may be

because boys are incorrectly coded as having phimosis. Incorrect diagnostic coding may be a result of clinicians making incorrect diagnoses, incorrect labelling of diagnoses e.g. clinicians noting down phimosis as a diagnosis when the procedure was really performed for ritual reasons, or the result of clinical coders incorrectly assigning diagnostic codes. This case study was unable to establish which of these reasons was more likely.

Apart from reporting incidence of circumcision, this case study also sought to use HES data to identify the determinants of outcome of the procedure. Complications occurring as a result of this particular surgery are relatively rare and as a result few studies have the power to comment on the determinants of outcome of the procedure. The HES database by its sheer size has ample power to identify such factors. However, one weakness of the HES database is the identification of complications following a procedure, as there are many different possible procedure diagnostic and procedure codes available that could potentially be used by clinical coders to record complications. Clearly, incorrect use of codes within our analysis would have led to under-reporting of complications.

To address this weakness inherent within the HES database, we specifically did not identify diagnosis and operative procedure codes relating to complications of circumcision in advance. Instead, we examined diagnosis and operative coding within HES records concerning admissions in which a complication was most likely to have occurred – i.e. index admissions in which the duration of in-hospital stay was longer than 24 hours and readmissions within 30 days. We then grouped these codes into different complication categories. By this process, we were able to account for inconsistencies in coding practice between hospitals.

A further weakness of the HES database is that for a complication to be captured, that complication must lead to a hospital admission. Complications not requiring readmission are therefore not accounted for. Superficial skin infection following any minor open urological procedure such as circumcision is arguably the most common complication, however HES data identified very few boys with this complication as it rarely led to hospital admission.

The third case study in this thesis utilised the HES database to report on the incidence of acute urinary retention. This study again highlighted, alike the case study concerning the incidence of hypospadias, the difficulty in identifying the index event. In this study, an episode of primary urinary retention was sought. However, labelling an episode the very first event was dependant upon the extent of database history available over which previous episodes may be sought. In attempt to negate this weakness, a weakness that could have led to artificial trends in the burden of urological disease over time, a predefined period of database history, a preceding period of 6 months within this particular case study, was used to determine if the event was truly a primary event. This is a key weakness that applies to all analyses of HES data when a primary event is required to be defined.

This weakness cannot be accounted for in the same manner for all conditions. In this thesis, the occurrence of a prior episode of retention was reviewed by looking at patients with multiple years of previous database history. It was identified that the vast majority of prior episodes occurred in the preceding 6 months. However, if one was trying to identify previous hernia repair surgery for example, to identify those undergoing primary hernia repair, many years of database history may need to be sought as hernia repairs would not be expected to fail immediately after primary surgery.

The fifth case study within this thesis evaluated the use of HES data to report on whether delay in cystectomy from initial diagnosis impacted on long-term survival. This study identified one fundamental weakness in the use of HES data to report on the determinants of outcome of surgery. HES data analysis suggested delay in surgery had no impact on long-term survival. This finding is at odds with the majority of the published literature on this topic and goes against what one would expect given that invasive bladder cancer requiring cystectomy is an aggressive cancer associated with a poor survival. This case study demonstrated that without linkage of HES data to other data sources, the HES database should only be used with caution when evaluating long-term cancer outcomes.

The sixth and final case study within this thesis evaluated the use of the HES database to drill down and uncover evidence as to how higher volume hospitals are able to

achieve improved short term outcomes of pelvic cancer surgery, a finding much reported but poorly understood. Conducting a randomised clinical trial in order to answer this clinical question would entail considerable costs and may be difficult to obtain ethical approval for. The comprehensive size, availability and detail concerning the administration of healthcare delivery held within the HES database lends itself to answering this question and those alike. The weakness of the HES database again concerns the identification and capture of complications or adverse events following surgery, however, this weakness was addressed in a similar manner as that described in the circumcision case study.

10.4 Comparison with other studies utilising databases other than HES to answer clinical relevant questions

A number of authors have reported on the use of administrative data, other than the HES data, for the purpose of reporting disease incidence. Sund reported on the use of Finnish administrative discharge data for just this reason. This detailed study, using hip fracture monitoring as an example application, attempted to identify issues that require 'rethinking' during the process of utilising secondary data for incidence reporting. Pitfalls identified included the assumption that for administrative data to identify 'cases', only hospitalised injuries are observable. The effect of which is case underascertainment resulting in underestimation of disease incidence if the medical condition is managed without requiring hospitalisation. Another pitfall identified by Sund related to multiple hospitalisations relating to the same patient with the subsequent difficulty in identifying which admissions should be considered readmissions. Additional pitfalls identified relate to difficulties in case definition, specifically the need to have detailed and specific clinical knowledge with regard to the medical condition of interest to enable case definition to be achieved by the use of complex aggregates of various different diagnosis and operative procedure coding.

In this thesis, we specifically tailored our use of HES data - when evaluating the HES data to answer questions considering the incidence of urological disease, to evaluate only those surgical conditions that required surgical intervention. Given that for an operation to be performed, the patient is required to be admitted to hospital, underascertainment caused by managing the condition without hospitalisation is not an issue. However, it is recognised that when reporting on the incidence of acute

urinary retention, a proportion of men may have been managed without hospitalisation. Furthermore, identification of index admissions from readmissions was a specific area that we addressed in this thesis. For example, when identifying the incidence of acute urinary retention in chapter nine, an episode of acute urinary retention was labelled a primary retention episode as opposed to a recurrent retention episode when there was no HES record documenting a previous episode of acute urinary retention in a preceding period of at least 6 months.

Finally, given the breadth of clinical knowledge at the CEU, as well as the process of case definition – cases were not identified in advance, diagnosis and operative procedure coding were instead reviewed to identify coding practice before aggregating a number of codes to generate and define ‘cases’, meant that the pitfalls associated with case definition, highlighted by Sund, were minimised within this thesis.

In addition to Finnish administrative discharge data, the US Medicare database has been utilised extensively to answer questions concerning incidence of disease in the US. Fisher and colleagues report on the pitfalls of epidemiological research using Medicare data, again using hip fracture as the example application. Fisher raises concerns over the use of Medicare data for such a purpose as substantial differences were identified between the characteristics of those in the Medicare population and those of the general population as documented by the US census. Fisher found that Medicare coverage varies substantially across age, gender and race groups. Although some of these differences were thought to be trivial, others were not. The study concluded that conclusions on incidence drawn from Medicare data, while they may be accurate for the Medicare population, should not necessarily be generalised to the elderly US population as a whole.

It has been reported that between 95 and 96% of the US elderly population are enrolled in Medicare [Lauderdale et al, 1993]. Systematic differences in enrolment across age, gender and race explain why Medicare does not reflect the general US population. However, if one considers the UK population, NHS coverage is thought to be significantly higher than 96%. However, there is some evidence, including data utilised from the HES database itself, to suggest there is some degree of inequality in

surgical services across the UK. It is therefore possible that such inequality, for example the availability or access to urological services, may have resulted in some degree of underascertainment and as such under estimation of disease incidence within this thesis.

Another limitation or pitfall associated with the use of administrative data, raised by Baron and colleagues in their review of medical databases for epidemiological research is the “rule-out” diagnosis. For example a patient is admitted for chest pain, the clinician investigates the patient for a possible diagnosis of Myocardial Infarction (MI). However, subsequent tests disprove the diagnosis of MI. However, when it comes to medical coding, although a diagnosis of MI was eventually disproved, a diagnosis of MI may still be coded with the administrative database, especially if no other diagnosis is subsequently made for the particular patient by the clinician.

In this thesis, for the main part, we utilised surgical procedures as the numerator which do not tend to be susceptible to “rule-out” bias. However, for acute urinary retention, even the passing of a catheter along with a diagnosis of retention does not confirm retention and as such, analysis of retention incidence is at risk of “rule-out” bias.

Lezzoni in an article entitled “assessing quality using administrative data” raises two further potential pitfalls. Limitation of the number of diagnosis and operative procedure fields can lead to underestimation of incidence. For example, in a complex admission in which a patient experiences many medical problems, the occurrence of urinary retention during admission may not be included in the admission record as there was insufficient space for the diagnosis code amongst the more severe medical conditions. This pitfall has been demonstrated by a recent study of Medicare data that identified chronic conditions were less likely to be coded when patients died during their admission as all the coding slots were consumed by acute diagnoses. This pitfall could influence the ability of administrative data to report incidence, not only in the Medicare database but also the HES database and is why both the Medicare and the HES database have expanded the number of diagnosis and operative fields available to clinical coders.

Lezzoni raises another issue with regard diagnosis coding, on this occasion specifically regarding the timing of events. Coding of diagnoses occurs after discharge. Differentiating the timing of each diagnosis is key to risk adjustment. For example, chronic renal failure and diabetes are obviously pre-existing conditions. However, pneumonia may be a pre-existing condition or an acute problem. In such a case, differentiating between acute and co-morbid conditions may be difficult. While this issue is more important when risk stratifying outcomes of surgery, it may influence estimation of disease incidence. In this thesis, we attempted to overcome this issue by utilising the HESID number to identify any previous episodes of care in which the particular diagnosis or operation of interest may be documented so as to identify *index admissions* - namely the first database documented record in which a particular operation or diagnosis occurred.

A number of authors have reported on the use of administrative data, other than the HES data, for the purpose of reporting outcomes of surgical activity. Lezzoni described the occurrence of “death creep” – reprising “code creep”, which has been reported to occur within the Medicare database if hospitals know that their discharge abstracts will be used to evaluate mortality rates. “Death creep” describes the practice whereby hospitals increase the coding of near-death conditions such as cardiac arrest and respiratory failure for example which have the effect of confusing efforts to risk-adjust mortality rates when making comparisons across hospitals.

While this phenomenon could potentially impact on our case study investigating how higher volume centres achieve improved outcome following radical pelvic surgery, it is unlikely to have been a major source of error in this thesis. First because medical coders coding for complications of surgery in 2002 were unaware that the surgical outcomes achieved by their individual hospitals were to be analysed, especially given that few studies were utilising HES data at this time to report outcomes of surgery and second, unlike their US counterparts, at least prior to the UK government initiating the Patient Choice agenda, hospitals in the UK were not competing against each other for work and as such revenue.

Another pitfall of administrative data to report and compare outcomes of surgery as identified by Ayanian, concerns its lack of information concerning disease severity or

stage of disease. The importance of this pitfall or limitation will of course depend on the surgical procedure being studied. For example, Lewsey et al utilised administrative data – linked hospital discharge and mortality data created by the Information and Statistics Division of the NHS in Scotland, to analyse and compare outcomes (1-year survival) of Percutaneous Transluminal Coronary Angioplasty (PTCA) and Coronary Artery Bypass Graft (CABG) surgery. As this data source lacked information about each patients' left ventricular function – the two most critical factors for determining short-term outcome of such procedures, questions have been raised concerning the ability of such data to compare outcomes of the two procedures. While cancer disease severity will not tend to influence short-term outcome measures such as 30-day mortality, the inability to adjust for this factor will certainly limit the use of HES data to compare long-term outcomes that in turn reflect the oncological outcomes achievable by different centres. This limitation is illustrated within this thesis in the case study investigating the impact of delay on long-term survival following radical cystectomy for bladder cancer. Furthermore, the lack of data concerning severity of co-morbid disease within any administrative database such as HES will affect attempts to risk-adjust mortality rates when comparing outcomes achievable by different centres.

10.5 Recommendations and conditions required prior to the use of HES data

Below are a list of recommendations that are derived from the lessons learnt from the review and case studies included within this thesis. These recommendations concern a number of conditions that must be met for the HES database to be considered a valid and so valuable source of information for the urologist.

1/ When incidence is to be calculated using the HES database, there must be *no* or *minimal* ambiguity regarding the diagnostic or procedural coding for a particular disease or a particular surgical intervention. If a condition or disease was not listed in the tenth revision of the International Classification of Diseases coding system (ICD-10), or the Offices of Populations Censuses and Surveys operative procedure coding system (OPCS-4), it is not possible to calculate disease incidence or surgical practice. All case studies within this thesis investigated surgical diseases and procedures that were coded for with minimal ambiguity. For example, hypospadias is a common

procedure that is coded with a single specific single OPCS-4 code while the diagnosis of hypospadias itself is again coded for with a single ICD-10 diagnosis code. When identifying other diagnoses or operative procedures, a number of codes can be used, however, all operative and diagnostic codes should not be identified in advance. Instead all diagnosis and operative codes listed within HES admission should be reviewed to identify specific coding practice employed by hospital coders. This recommendation is supported by case studies reporting complications of circumcision and radical cystectomy. Both case studies dramatically increased the number of complications recorded within HES records by reviewing coding practice rather than identifying diagnostic and operative codes in advance. Adherence to this recommendation, the investigative urologist may reliably define a diagnosis or a treatment/intervention that can be “operationalised” using a number of available HES codes.

2/ If incidence of a condition is to be based on treatment identified from the HES database, all or certainly the majority of patients must undergo treatment for that condition. Furthermore, all or certainly the majority of patients with a particular diagnosis must be hospitalised. Finally, if hospitalisation is to occur, all or the majority of patients must be hospitalised within an NHS hospital. These recommendations are supported by the case studies concerning the incidence of hypospadias and the incidence of acute urinary retention. If the majority of boys with hypospadias did not undergo surgery for their congenital anomaly, incidence estimates based on treatment would be incorrectly low. If the majority of men with acute urinary retention as a result of BPH progression had not been admitted to hospital, it may not have been possible to evaluate the impact of change in the management of BPH. Furthermore, if a high proportion of both boys undergoing surgery for hypospadias, or men experiencing acute urinary retention were treated outside the NHS, incidence estimates would again have been incorrectly low.

3/ When the HES database is to be used as a source of data to report incidence of a particular condition prior to the introduction of HESid numbers, indiscriminate use of Finished Consultant Episodes (FCE's) should be avoided due issues of double-counting which lead to over-estimation of disease incidence. Instead, researchers

should use a combination of date of birth, postcode, discharge destination, as well as episode order in order to identify patient level data.

4/ When the HES database is to be utilised as a source of information concerning clinical appropriateness of treatment, the prevalence of that condition must be known. This recommendation is supported by our case study concerning clinical appropriateness of circumcision. Without a well-documented incidence of phimosis being known, the HES database could not have been used to identify that too many boys undergo unnecessary surgery.

5/ The HES database would appear ideally suited to monitoring trends over time in incidence and practice of surgery as well as changing trends in outcome of surgery. However, for trends to be interpretable, there must be no changes in coding practice over time. For example, in the case study concerning circumcision, boys noted to have undergone ritual circumcision increased over the study period (these boys were excluded from our analysis, the number of boys being excluded for this reason were seen to increase over time). This may have been because boys were increasingly undergoing ritual circumcision or because coders were more likely to use this code. A change in the structure of the HES database may also influence trends. For example, after 2002, the number of diagnosis and procedure fields increased to 14 and 12, from 7 and 4 respectively. This increase allows coders to code for more diagnoses and operative procedures that could in-turn suggest a rising incidence of disease. Care should therefore be taken when interpreting trends in incidence using HES data around this time although analyses of case studies in this thesis have not suggested a sudden increase or decrease in disease incidence over this particular time.

6/ The HES database should not be used as a source of data in isolation to report long-term oncological outcomes of surgery. This recommendation is supported by the case study investigating the impact of delay on outcome of radical cystectomy as HES data did not identify that patients experiencing prolonged delay for treatment had an inferior outcome, a finding at odds with the majority of data published on this issue. Linkage with pathological data sources may on the other hand aid the use of the HES database to report and investigate such outcomes.

7/ HES data may be used to investigate the determinants of short-term surgical outcome. This recommendation is supported by the case study investigating how high volume hospitals achieve improved outcome. This case study used HES data to identify that high volume hospitals achieve improved outcome following radical pelvic cancer surgery – a finding compatible with the majority of data published on this topic.

8/ To maximise the value of HES to report on the processes and outcomes of surgery, outcome measures other than hospital mortality should be evaluated. This recommendation is supported by the review that identified other indices of quality available within HES. These include – the percentage of FCE's with a coded complication - identified by searches of HES records to identify diagnostic and operative coding adverse events, the percentage of FCE's with a prolonged length of stay, mean length of spell and the percentage of FCE's in which patients undergo more than one operative procedure.

10.6 Clinical Questions suited to HES data

HES data is suited to asking questions concerning common conditions that are easily defined and diagnosed without ambiguity which can subsequently be easily coded for, such as hypospadias. Treatment for such conditions/diseases should again be easily defined and coded for, again alike hypospadias. On the other hand, conditions/diseases for which multiple different treatments are available are best avoided as defining treatment will be complicated. Questions concerning incidence of disease are suited to HES data due to its comprehensive nature given that the majority of people in England receive medical treatment within NHS hospitals.

The HES database does also lend itself to answering questions regarding the clinical appropriateness of treatment as in the case study of circumcision and phimosis, again given its comprehensive nature, providing the prevalence of the medical condition that is being treated is known.

The HES database may also be useful in answering questions concerning the real-life impact of change in the management of clinical diseases. While the randomised

controlled trial is the gold standard research methodology and has been used on many occasions to identify that one treatment may be better than another, HES data may be used to evaluate the real-life impact of adopting treatments advocated by such trials. This is demonstrated by the case study on the impact of a shift away from surgery for men with BPH on the incidence of acute urinary retention. Of course, the outcome measure of disease progression would have to require hospital admission.

HES data may be used to answer questions concerning outcome of surgery providing the outcome of interest requires hospital admission and again is coded for e.g. post-operative mortality. Identifying the determinants of outcome such as erectile dysfunction following radical prostatectomy for prostate cancer for example is not suited to the HES data as first the outcome does not require hospital admission for treatment and second, it not easily coded for within the database.

HES data does not suit questions concerning specific cancer-related outcomes as demonstrated by the case study concerning impact of delay of radical cystectomy for patients with bladder cancer but on the other hand is suited to asking administrative questions such as is delay in surgery occurring? Answering such questions can help improve cancer services as it can lead to the targeting of services and the improvement in healthcare delivery.

Indeed, HES data is particularly suited to answering questions concerning structure of healthcare and the improvement of healthcare provision chiefly because investigation of outcome on a hospital level can be performed. For example, HES was able to identify that improving the management of complications following radical pelvic surgery may enable lower volume centres to improve their outcomes. HES on the other hand does not lend itself to the identification of the determinants of outcome for individual surgeons.

Finally, the review suggests HES data is ideally suited to investigating Healthcare Needs Assessment, a topic for which the HES database has been utilised most often to date. The main attribute the HES database has for this purpose is its national coverage together with its high ascertainment.

10.7 Future Directions

Future research concerning the possible uses of HES data to answer clinically pertinent questions is essential as the HES database represents a rich, available and cost-effective medical research resource.

With specific respect to the HES database, future research is needed to better understand the completeness, reliability and timeliness of HES data, on which the value of HES data to epidemiology rests. Further studies are needed on the accuracy and validity of HES data.

Such validation studies may be either performed by directly comparing HES data records with medical notes or alternatively, HES data can be compared with pre-existing large national audits that have been commissioned either by the UK government or by the individual medical colleges. An example would be the National Prospective Tonsillectomy Audit (NPTA). This audit was commissioned by the British Association of Otolaryngology specifically to investigate the determinants of post-tonsillectomy haemorrhage. Direct comparison could be performed between HES data and NPTA data. Not only would such comparison studies evaluate the accuracy of HES data, they would also evaluate to what extent the HES database could be subsequently used for '*continual monitoring of surgical outcomes*' as opposed to periodically repeating these national audits which are known to be both highly expensive and labour-intensive.

The Clinical Effectiveness Unit is in an ideal position to undertake such research as it has developed extensive expertise in the processing and analysis of HES data while it also conducts many of the national audits such as the NPTA on behalf of the individual speciality associations.

Further work is also ongoing at the Department of Health to develop a *Spells Universe* (expected to be made available by autumn 2007). As alluded to on multiple occasions through out this thesis, it is essential to recognise that episodes of care (FCE's) do not represent patient level data and as such should be processed in such a way that individual patient level data be generated. Although each spell still does not equate to

patient level data (when a single patient is readmitted, a second spell will be generated), the use of a Spells Universe would certainly make HES data processing and analysis easier for the medical researcher.

In addition, the Department of Health has recently started collecting data within the HES database concerning outpatient consultations. Information gleaned from these data have yet to be the topic of a research publication. However, the collection of such data would enhance the usefulness of the HES database to answer clinically significant questions. A number of conditions, such as urinary incontinence for example, although potentially treatable by surgery, may also be treated, at least initially, by alternative treatment strategies. Identifying patients in the outpatient setting would enable not only the incidence of the condition to be estimated, but also enable the natural history of the condition to be established and monitored.

Further work is also required to link the HES database with additional databases. This is again vital work as linkage, if accurate, will only increase the usefulness and power of the HES database. Currently work is underway linking the HES database with regional cancer registries as well as national radiotherapy databases (Bristol).

Finally, with the publication of the Darzi report in 2008, increasing emphasis will be placed on improving the quality of care provided by the NHS. Data concerning all three tenets of quality – patient safety, patient experience and effectiveness of care, will increasingly be required to be made available within the public domain. HES data is likely to be used increasingly for such purposes. Future work using HES data is likely to focus on the identification of HES derived “*quality indicators*” that can be used to monitor the quality of surgical care within the UK.

12.7 Concluding comments

Growing emphasis has been placed by on clinical governance and assessment of clinicians outcomes, especially those of surgeons, the importance of which is recognised by government, the general public and the medical profession alike. Despite this, there is a lack of data available on patient outcomes after surgical care in the UK. As a result the Clinical Effectiveness Unit of the Royal College of Surgeons

of England has sought to evaluate alternative data sources that could be used to study the “epidemiology of the quality of surgical care”. Part of this body of work is contained within this thesis. The overall objective of this thesis was to evaluate if the HES database could be used as an alternative data source to answer questions of clinical relevance to the urological surgeon.

This thesis has utilised a number of case studies together with a review of the published literature to identify the strengths as well as weaknesses of the HES database for such a purpose. While some of these strengths and weaknesses are specific to the particular case studies included within this thesis, others are relevant to general use of HES data as a whole. Such analysis has enabled the development and formation of a number of key recommendations that need to be met before the urologist can use the HES database as a valid and valuable source of information from which clinical questions can be asked.

HES data does hold considerable promise for the clinical researcher as an untapped source of data. However, alike all data sources, HES data is only as good as the question asked of it. This would appear the key point. The HES database will only be useful provided appropriate questions are asked in light of its strengths and weaknesses.

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Appendices

Appendix 1

HES Extract Pack Application form for circumcision data

(Please either type or write in black ink, as this form will be photocopied)

Data years (please tick):

1989/90	1990/91	1991/92	1992/93	1993/94	1994/95
1995/96	1996/97	1997/98	1998/99	1999/00	2000/01
2001/02	2002/03	2003/04			

Filter details (see 2.3.1 to 2.4.1)

Epistat=3

OPER_1-4=N303

To identify these episodes and all subsequent episodes over a period of 1 year following initial surgery. Individual patients will need to be identified using a unique anonymous patient identifier based on DOB, SEX and HOMEADD.

Fields to be extracted (please tick):

Please note that the fields below are of the **General Table**, for Augmented Care, Maternity and Psychiatric A fields. Please refer to the Data Dictionary and write down the selected fields in Other Details on page 17.

Data Dictionary: <http://tap.ccta.gov.uk/doh/hes>

ADMIDATE
(Date of Admission)

DIAG 6
(Diagnosis)

HOMEADD
(postcode of patient)

ADMIMETH
(Method of Admission)

DIAG 7
(Diagnosis)

HOTEL
(cost per day)

AMDICAT
(Admission Category group)

DISDATE
(Date of discharge)

HRGLATE
(desc. of healthcare resource)

ADMISORC

DISDEST

HRGORIG

(Source of Admission)	(Destination of discharge)	(healthcare resource group)
ADMISTAT (psychiatric patient status)	DISMETH (Method of discharge)	INTMANIG (Intended management)
AIDSIND (aids flag)	DOB (Date of birth)	LAGLAT (legal category)
BEDYEAR (Bed days within year)	ELECDATE (Date of decision to admit)	LOPATID (local patient identifier)
CARERSI (carer support indicator)	ELECDUR (Waiting time)	MAINSPEF (main speciality)
CATEGORY (psychiatric patient status)	ENDAGE (Age at the end of episode)	MARSTAT (marital status)
CAUSE (External cause of injury)	EPIDUR (Episode duration)	NEOCARE (neonatal level of care)
CLASSPAT (Patient classification)	EPIEND (Date episode ended)	NEODUR (babies age in days)
CURWARD + RESLADST (Current Electoral ward)	EPIKEY (System record identifier)	NEWNHSNO (NHS number)
DETNCAT (Detention category)	EPIORDER (Episode order)	NUMACP (No. of augmented care periods)
DHATREATHA (District of treatment)	EPISTART (Date episode started)	OPER_1 (contains information about patients operation)
DHACOMP_HA (DHA comparison)	EPITYPE (Type of episode)	OPER_2 (contains information about patients operation)
DIAG_1 (Diagnosis)	GPPRAC (Code of G.P. practice)	OPER_3 (contains information about patients operation)
DIAG_2 (Diagnosis)	GPPRACHA (Health authority of G.P. practice)	OPER_4 (contains information about patients operation)
DIAG_3 (Diagnosis)	GPPRACRO (Regional office of G.P. practice)	OP_DTE_1 (Date of operation)
DIAG_4 (Diagnosis)	GROSS_A (Clinical grossing)	OP_DTE_2 (Date of operation)
DIAG_5	GROSS_B	OP_DTE_3

(Diagnosis)

(Combined coverage & clinical grossing) (Date of operation)

OP DTE 4
(Date of operation) -

Appendix 2

Business Objects online HES Interrogation System Query for Hypospadias data

Universe:

1997/1998 (*subsequent universes thereafter until 2004/2005*)

Objects:

ALL DIAGNOSES
ALL OPERATIVE PROCEDURES
EPISODE DURATION
SEX
DATE OF BIRTH
ADMISSION DATE
DATE OF DISCHARGE
EPISODE START DATE
EPISODE END DATE
AGE AT END OF EPISODE
EPISODE ORDER
MAIN SPECIALITY
BABIES AGE IN DAYS
ALL DATES OF OPERATION
HESID NUMBER
PATIENT AGE

Condition Objects:

ALL DIAGNOSES BETWEEN “Q54” AND “Q55”
AND
FINISHED CONSULTANT EPISODES (FCE’s)

Definitions:

Universe – a logical grouping of classes. It corresponds to an individual HES datayear.

Object – elements in the Business Objects universe that correspond to a selection of data within the HES database. **Objects** within the HES database correspond to the **fields** of the HES database e.g. ADMIMETH. However within the framework of Business objects, HES objects are given descriptive names e.g. admission method=ADMIMETH.

Appendix 3

Business Objects online HES Interrogation System Query for BPH-related surgery data

Universe:

1990/1991 (*subsequent universes thereafter until 2002/2003*)

Objects:

ALL DIAGNOSES
 ALL OPERATIVE PROCEDURES
 EPISODE DURATION
 SEX
 DATE OF BIRTH
 ADMISSION DATE
 DATE OF DISCHARGE
 EPISODE START DATE
 EPISODE END DATE
 AGE AT END OF EPISODE
 EPISODE ORDER
 ALL DATES OF OPERATION
 HESID NUMBER
 PATIENT AGE

Condition Objects:

ALL OPERATIONS BETWEEN "M65" AND "M66"
 OR
 ALL OPERATIONS BETWEEN "" AND ""
 AND
 FINISHED CONSULTANT EPISODES (FCE's)

HES data obtained from this Business Objects query was subsequently linked to the HES data gained from the Business Objects query identifying men experiencing urinary retention (appendix 4) to enable "outcome of BPH-related surgery", to be reported on.

Appendix 4

Business Objects online HES Interrogation System Query for urinary retention data

Universe:

1997/1998 (*subsequent universes thereafter until 2003/2004*)

Objects:

ALL DIAGNOSES
 EPISODE DURATION
 SEX
 DATE OF BIRTH
 ADMISSION DATE
 DATE OF DISCHARGE
 EPISODE START DATE
 EPISODE END DATE
 AGE AT END OF EPISODE
 EPISODE ORDER
 ALL DATES OF OPERATION
 HESID NUMBER
 PATIENT AGE

Condition Objects:

ALL DIAGNOSES BETWEEN "R33" AND "R34"
 AND
 FINISHED CONSULTANT EPISODES (FCE's)

Appendix 5

HES Extract Pack Application form for Radical Urological Pelvic surgery data

(Please either type or write in black ink, as this form will be photocopied)

Data years (please tick):

1989/90 1990/91 1991/92 1992/93 1993/94 1994/95
 1995/96 1996/97 1997/98 1998/99 1999/00 2000/01
 2001/02

Filter details (see 2.3.1 to 2.4.1)

Epistat=3

OPER_1-4=M02 AND DIAG_1-7=(C64 OR C65)

OPER_1-4=M34 AND DIAG_1-7=C67

OPER_1-4=M61 AND DIAG_1-7=C61

OPER_1-4=M03 AND DIAG_1-7=(C64 OR C65)

To identify these episodes and all subsequent episodes over a period of 2 years following the initial surgery and all episodes over a period of 2 years prior to admission for initial surgery. Individual patients will need to be identified using a unique anonymous patient identifier based on DOB, SEX and HOMEADD.

Fields to be extracted (please tick):

Please note that the fields below are of the **General Table**, for Augmented Care, Maternity and Psychiatric A fields. Please refer to the Data Dictionary and write down the selected fields in Other Details on page 17.

Data Dictionary: <http://tap.ccta.gov.uk/doh/hes>

ADMIDATE
(Date of Admission)

DIAG 6
(Diagnosis)

HOMEADD
(postcode of patient)

ADMIMETH
(Method of Admission)

DIAG 7
(Diagnosis)

HOTEL
(cost per day)

AMDICAT
(Admission Category group)

DISDATE
(Date of discharge)

HRGLATE
(desc. of healthcare resource)

ADMISORC
(Source of Admission)

DISDEST
(Destination of discharge)

HRGORIG
(healthcare resource group)

ADMISTAT (psychiatric patient status)	DISMETH (Method of discharge)	INTMANIG (Intended management)
AIDSIND (aids flag)	DOB (Date of birth)	LAGLAT (legal category)
BEDYEAR (Bed days within year)	ELECDATE (Date of decision to admit)	LOPATID (local patient identifier)
CARERSI (carer support indicator)	ELECDUR (Waiting time)	MAINSPEF (main speciality)
CATEGORY (psychiatric patient status)	ENDAGE (Age at the end of episode)	MARSTAT (marital status)
CAUSE (External cause of injury)	EPIDUR (Episode duration)	NEOCARE (neonatal level of care)
CLASSPAT (Patient classification)	EPIEND (Date episode ended)	NEODUR (babies age in days)
CURWARD + RESLADST (Current Electoral ward)	EPIKEY (System record identifier)	NEWNHSNO (NHS number)
DETNCAT (Detention category)	EPIORDER (Episode order)	NUMACP (No. of augmented care periods)
DHATREATVIA (District of treatment)	EPISTART (Date episode started)	OPER_1 (contains information about patients operation)
DHACOMPUA (DHA comparison)	EPITYPE (Type of episode)	OPER_2 (contains information about patients operation)
DIAG_1 (Diagnosis)	GPPRAC (Code of G.P. practice)	OPER_3 (contains information about patients operation)
DIAG_2 (Diagnosis)	GPPRACHA (Health authority of G.P. practice)	OPER_4 (contains information about patients operation)
DIAG_3 (Diagnosis)	GPPRACRO (Regional office of G.P. practice)	OP_DTE_1 (Date of operation)
DIAG_4 (Diagnosis)	GROSS_A (Clinical grossing)	OP_DTE_2 (Date of operation)
DIAG_5	GROSS_B	OP_DTE_3

(Diagnosis)

(Combined coverage & clinical grossing) (Date of operation)

OP_DTE_4
(Date of operation) -

Appendix 6

Review literature search strategies

Database Search strategies (Medline)

Database Terms

- 1 Hospital episode statistics.mp.
- 2 exp Hospital record\$ /
- 3 hospital admiss\$ adj25 NHS.mp
- 4 hospital admiss\$ adj25 record\$.mp
- 5 hospital adj25 episode\$.mp
- 6 routine adj25 statistic\$.mp
- 7 Discharge statistic\$.mp.
- 8 Hospital statistic\$.mp.
- 9 Routine data.mp.
- 10 Link\$ adj25 record\$.mp.
- 11 ((Death record\$ or death certif\$) adj25 hospital admiss\$).mp
- 12 (medical record\$ adj25 references database).mp
- 13 or/1-12

16,651 references

Appendix 7

Diagnostic and Operative procedure codes used to identify and record complications following circumcision

Complication	International Classification of Diseases (ICD-10) Code	UK Tabular List of the Classification of Surgical Operations and Procedures (Offices of Populations, Censuses and Surveys – OPCS-4)
Haemorrhage	T810, T812, T811, T817, N501, Y60, Y608, S302.	^a Y321, Y712, Y228, Y111, Y252, Y321, Y221, N322, S424, Y712, Y228, Y111, Y252, Y321, Y221, N322, S424 X32, X328, X329.
Infection	N482, N482.	
Other acute complication (e.g. post-op. retention)	R33X, R391, T795, T813, T888, T889, Y69, Y838, Y839.	M478, M479.
Meatal Stenosis		N79

^a Italics: OPCS-4 codes used to identify return to theatre for surgical arrest of haemorrhage

Appendix 8

Diagnostic and Operative procedure codes used to identify and record complications following radical cystectomy

Complication	International Classification of Diseases (ICD-10) Code	UK Tabular List of the Classification of Surgical Operations and Procedures (Offices of Populations, Censuses and Surveys - OPCS-4)
Bacteraemia	A047, A415, A419, A490, B956, B968, R509, A412, A410, Z223, N10.	
Acute Cardiac Event	I21, I219, I22, I23, I509, R074, I209, I48, I500, I509, I501.	
Pulmonary Embolism	I26, I269.	
Cardiac/ Respiratory Arrest	I46, R092.	
Cardiovascular Accident (CVA)	I693, I694, I65, I632.	
DVT	I801, I802, I803, I808, I809, I822, I828, I829.	

Pneumonia	J069, J13, J14, J15, J17, J18, J209, J22, J69, J869.	
Respiratory Compromise	J80, J81, J90, J91, J93, J938, J939, J942, J958, J959, J960, J969, J981.	T124, T122.
Gastro-Intestinal Haemorrhage	K228, K625, K920, K921, K922, K265, K261.	
Bowel Obstruction	K56, K565, K566, K567, K66, K660, K668, K913, K918, K919, K913.	T30, T301, T302, T309, T413.
Rectal Perforation	K628.	H468, H468.
Peritonitis/Pelvic Abscess	K630, K631, K650, K658, K659, T814, T815.	T452.
Superficial Wound Infection	L022, L03, L033, L039.	S472, S572.
Acute Renal Failure	N17, N179, N19, N990, K767, E875, E872.	
Complications 2nd ileostomy	N995, T831, T835.	

Operative Complications	T810, T812, T813, T818, Y838, I978, I979, R58, R57, T811, D65.	J692, J699, J724, T283, Y251.
Other (e.g. post-procedure nausea and vomiting)	N99, R69, K559, K550, M801, K632, R100, T819, R410, R11.	T318.

